# ANNEX 1

# TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 1 -

## *Advanced Sensing, Control, and Platforms for Manufacturing*

## Overview

The Advanced Manufacturing Partnership 2.0 (AMP2.0) provided recommendations in the full report to which this letter report is an annex. In that full report, AMP2.0 provided recommendations under the pillar of Enabling Innovation to strengthen manufacturing technology innovation. This effort included the process by which AMP2.0 identified Manufacturing Technology Areas (MTAs) of high national priority, as detailed in Appendix 1. Annexes 1-10 provide more detailed supporting information on the three MTAs that were prioritized via that AMP2.0 process. Annexes 1-2 focus on Advanced Sensing, Controls, and Platforms for Manufacturing (ASCPM); Annexes 3-6 focus on Visualization, Informatics, and Digital Manufacturing (VIDM); and Annexes 7-10 focus on Advanced Materials Manufacturing including three specific subsets. The recommendations for these three MTAs are summarized in Table 1 of the full report, and the process by which AMP2.0 developed these MTA analyses is described in Appendix 1.

AMP2.0 has developed a series of letter reports that recommend U.S. action to strengthen manufacturing technology areas (MTAs) of high-priority, and that provide supporting material for the recommendations. One of these high-priority MTAs is the broad area of **Advanced Sensing, Control, and Platforms for Manufacturing (ASCPM)**. A new generation of networked based information technologies, data analytics and predictive modeling is providing unprecedented capabilities as well as access to previously unimagined potential uses of data and information not only in the advancement of new physical technologies, materials and products but also the advancement of new, radically better ways of doing manufacturing. In focusing on the manufacturing or production stage of the product lifecycle, ASCPM technologies are strategically as important for U.S. manufacturing as are the design, new product and digital thread technologies. They offer the technical elements needed in smart manufacturing that is about enabling seamless interoperation of cyber and physical assets to increase productivity, product and process agility, environmental sustainability, energy and raw material usage, and safety performance as well as economic performance—and thereby comprehensively improve the competitiveness of the nation's factories and fulfill the Administration's goals for advanced manufacturing.

We interpret ASCPM to encompass machine-to-plant-to-enterprise-to-supply-chain aspects of sensing, instrumentation, monitoring, control, and optimization as well as hardware and software platforms for industrial automation. Although significant success has been achieved in manufacturing implementations with ASCPM, for a variety of reasons, the U.S. manufacturing industry has not come close to realizing the full potential of these technologies. These reasons include technical shortcomings of the state of the art as well as nontechnical barriers.

This letter report summarizes the broad manufacturing technology area (MTA) termed Advanced Sensing, Controls & Platforms for Manufacturing. The subsequent letter report, Annex 2, addresses the technical gaps in each of these areas in greater detail.

## Background

### *ASCPM Technologies are central to Productivity and Economic Growth*

A successful manufacturing industry is a powerful driver of productivity and economic growth, making tremendous contributions to trade, research and development, and more.

In the U.S., *manufacturing's share of productivity growth is three times its share of U.S. employment* and advances in efficiency and technology have *limited increases in the cost of durable goods to a tenth of the rate of consumer price inflation*[1] . In order to continue to capture these economic benefits, especially given its aging population and the resulting fall in labor force participation, the U.S. will need to accelerate productivity growth by more than 30%, achieving a rate not seen since the 1960s, to maintain historic growth rates per capita of GDP. The U.S. must create and exploit comparative advantages to convince the most globally competitive and productive companies to participate in the economy and to support the equally important contribution of small- and medium-sized manufacturing enterprises. Advanced Sensing and Measurement, Process Control and Optimization and Platforms for Manufacturing (ASCPM) technologies are strategically important for U.S. manufacturing and central to the productivity challenge; they can improve the competitiveness of the nation's factories by improving productivity and quality, leverage advantages in higher education, addressing issues that have led to off-shoring of plants and jobs, and help fulfill the Administration's goals for advanced manufacturing.

### *ASCPM Technologies are keys to Energy Efficiency and Renewables Integration*

The Energy sector, which leverages many similar technologies in advanced manufacturing, is projected to generate $380-690Bn of incremental GDP by 2020. As a general sense of the potential and scale associated with energy use in manufacturing, the U.S. consumed over 19,000 trillion BTUs across manufacturing sectors including chemicals, oil and gas, heat treating, biofuels, steel, cement, food and beverage industries.[2] Based on a 2011 analysis by the Smart Manufacturing Leadership Consortium (SMLC)[3], using a consumption of 10,000 trillion BTUs, approximately 1/3 is attributable to waste heat of which an estimated half could be saved. If realized, a savings of about 10% of the total would reduce annual $CO_2$ emission by 60-70 million tons per year.[4] Just on electricity consumption alone, according to the EIA, the top three industrial sectors are chemicals, primary metals, and paper, each with annual consumptions of 100+ to 200+ billion kWh. Tens of millions of tons of $CO_2$ reduction can be achieved with 10% or less reduction in industrial electricity consumption. *For example,* the U.S. chemical industry consumes 5 quadrillion BTUs of energy (5.9% of U.S. primary energy consumption), so energy efficiency improvements play a vital role in

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[1] McKinsey analysis

[2] http://www.eia.gov/consumption/manufacturing/

[3] The SMLC is a non-profit industry-led coalition comprised of manufacturers, IT providers, manufacturing consortia, universities, government laboratories and agencies and regional consortia http:/smartmanufacturingcoalition.org

[4] Compiled by the Smart Manufacturing Leadership Coalition from multiple literature reports: Energy Use, Loss and Opportunities Analysis, U.S. Manufacturing and Mining, U.S. Department of Energy Report, 2004; http://www.eia.gov/cneaf/electricity/epa/epata3.html, last retrieved 11/23/2011; Net Energy Balance of Ethanol Production, Ethanol Across America, http://www.ethanol.org/pdf/contentmgmt/Issue_Brief_Ethanols_Energy_Balance.pdf, last retrieved 11/23/2011; G. E. Totten, Heat Treating in 2020: What are the most Critical Issues and What will the Future Look Like?, Heat Treatment of Metals, 2004.1, 1-3, 2004; Renewable Fuels Association production statistics, http://www.ethanolrfa.org/pages/statistics#E, last retrieved 11/23/2011; A. G. Thekdi, Energy Efficiency Improvement Opportunities in Process Heating for the Forging Industry, Forging Industry Energy Workshop, Canton, OH, 2010.

sustainably employing energy. A recent global chemical industry technology roadmap describes the potential to save 13 quads of energy and 1 Giga ton (Gt) of $CO_2$ by 2050 via improvements in catalytic processes as overall production more than doubles.

For the U.S., improvements across incremental, best-practice technology deployment and emerging technologies could approach 1.4 quads/yr [5]. To achieve these gains "energy-holistic" advances will be needed, including advanced sensing and control. Broader application of ASCPM technologies has great potential in the energy intensive manufacturing sectors as illustrated by some of the examples below.

- With advanced sensing and model-based optimization techniques, an aerospace metal-parts manufacturer expects to save on the order of $3 million per year, in its plant that includes both continuous and discrete processes, on furnace operations alone.
- A chemicals company projects 10-20% energy savings for a hydrogen production plant with improved sensors and modeling, translating to a reduced natural gas cost of $7.5M per year.
- A plant provides ancillary power services for the Independent System Operator (ISO), using demand-response and direct load control for frequency regulation of the grid. Reported revenue to the plant is over $1M annually.
- A three-mill cement grinding plant reduced specific energy consumption by as much as 5% with a customized model-predictive control approach.
- A robotic assembly plant for a large OEM anticipates reducing energy consumption by 10-30% using optimization tools for robot motion planning.

### *ASCPM is integral to the implementation of Big Data and Analytics in manufacturing*

Manufacturing is entering a period of substantial innovation and change driven by factors such as new materials, the commercialization of digital design and smart manufacturing technologies, increased integration of sensors into production equipment, and advances in robotics and automation and new information technologies. New forms for gathering data and generating 'soft' intelligence are emerging such as Big Data, the 'Internet of Things' and the growth of cloud-based implementations. The combination of these advances with increases in computing power is enabling advanced analytical approaches to generate value from this wealth of new data and information. Big Data, which is forecast to stimulate U.S. GDP by $155-325Bn by 2020, of which manufacturing is expected to be a major contributor, has the potential to generate significant productivity improvements, thus stimulating innovation and entrepreneurship. Extensive application of data-based intelligence is a U.S. competitive advantage that can be significantly leveraged to help the manufacturing sector, especially small and medium enterprises, by providing access to advanced capabilities in a cost and time efficient manner.

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[5] Technology Roadmap: Energy and GHG Reductions in the Chemical Industry via Catalytic Processes, International Energy Agency, June 2013. https://www.iea.org/publications/freepublications/publication/name,40309,en.html

Advances in ASCPM will be critical to capturing, sharing and processing this abundance of data and enabling benefits such as improved equipment reliability, productivity gains and improvements in safety, quality and yield, increased innovation and agility with new and value-add products and managing the environment and core energy and materials resources. These benefits will exist across a broad range of industries, from oil & gas to pharmaceuticals, automotive and aerospace to food production. Without a leadership position in these technologies the U.S. will run the risk of missing this next wave of manufacturing innovation.

*Consequently, the AMP 2.0 Technology Working Team considers ASCPM a priority area for investment and application, as this is as much about the transformation of manufacturing as it is about the adoption of new technologies and is interlinked with other initiatives in advanced manufacturing.* This letter report discusses the domestic and international landscape, broader vision, and key gaps and challenges in the ASCPM technology area, which, if overcome, can lead to broader adoption and value creation, and makes recommendations on potential models to address these gaps.

## Scope of Work

Small and Medium Enterprises (SME) account for 19% of manufacturing sales and 13% of manufacturing exports in the U.S. However these figures are much lower than Germany where SMEs account for 40% of manufacturing sales and one third of exports. Furthermore, the productivity gap between large and small manufacturers has increased over the years in the U.S. For example, the average value-added per employee in SMEs was about 80 percent of that of large establishments in the 1960s, but by the late 1990s, value-added per employee in SMEs was on average less than 60 percent of large establishments. These productivity gaps occur in part because SMEs tend to invest less in equipment[6] and are less likely to adopt new business and manufacturing practices than large firms AND small manufacturers often lack the resources, scale, experience, or wherewithal to stay abreast of the latest emerging technologies, manufacturing processes, or business management practices.

In contrast, 60 percent of Germany's manufacturing sectors are in medium-high technology or high-technology product areas, which mainly reflects the great strengths of Germany's 'Mittelstand'. These percentages are reversed in the United States, having about 60 percent of their manufacturers in low- or medium-low technology sectors and 40 percent in higher-tech ones. Similarly, due to strong manufacturing SMEs, Germany's export of research-intensive products as a share of GDP is almost seven times greater than the United States research intensive exports.

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[6] Connecting Small Manufacturers with the Capital Needed to Grow, Compete and Succeed: Small Manufacturers Inventory and Needs Assessment Report, November 2011, MEP, NIST

E.U. nations are investing significantly in ASCPM technologies, in what they refer to as Industrie 4.0 and with a powerful combination of public and private funding to advance the development and deployment of these technologies[7].

### *Vision*

ASMPC technologies will result in significant near-term benefits to the U.S. The overall vision for the U.S. is to achieve broader adoption, especially among SMEs, of these technologies to drive quality, yield, productivity, and energy efficiency gains both within and through interoperability. We also envision developing next generation ASCPM hardware and software technologies to translate the digital technology revolution to the manufacturing shop floor and to develop and demonstrate sustainable mechanisms for rapid technology transition from early stage research to large scale adoption by the manufacturing community.

We envision that within about five years, manufacturing-intensive companies will recognize the U.S. as the pre-eminent source of innovation in ASMPC. Over this duration, we also expect that the footprint of ASMPC technologies in discrete manufacturing will begin to attain that of the continuous process industries.

In the longer term, ASMPC will truly revolutionize manufacturing. New manufacturing processes would be optimally designed simultaneously with their sensor and actuator suites and control strategies. End-to-end supply/demand chains would be integrated and optimized in real-time. New sectors such as biomanufacturing and nanomaterials will be operationally mature in their application of sensing and control and in their automation platforms. The resurgence of US manufacturing will be driven in great part by ASMPC advances.

More specifically, one could envision specific goal statements related to ASCPM technologies such as those listed below.

- Manufacturing automation equipment from different vendors seamlessly interoperates and allows plug-and-play configurations within three to five years.
- Energy use and waste streams per unit output from manufacturing plants are reduced by twenty percent in three years and fifty percent in ten years.
- The deployment cost of sensors fall by an order of magnitude, enabling pervasive and comprehensive real-time measurement solutions including critical process parameters within five to ten years.
- Process optimization and control systems, automatically and in real-time, adapt to changes in feedstock, market demands, and plant performance within five to ten years.
- Potential faults and failures are detected and corrected when still incipient, reducing plant downtimes by fifty percent in five years and ninety percent in ten years.

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[7] 'Factories of the Future'_ Public Private Partnership Factories of the Future (FoF) is a EUR 1.2 billion programme in which the European Commission and industry are collaborating in research to support the development and innovation of new enabling technologies for the E.U. manufacturing sector, with many projects related to ASCPM technologies.

- Data and information platforms provide extensive access, scalability, reusability and actionable orchestration of analytic, modeling, simulation and performance metric software resources.
- Manufacturing facilities are a crucial nationwide resource for increasing renewables integration and grid reliability, and play a pivotal role in helping manufacturing-intensive states meet their Renewable Portfolio Standards (RPS) goals - large p*l*ants in five years, SMEs in ten to fifteen years.

### *Implementation Challenges*

*The following system-level factors currently inhibit implementation of ASCPM technologies, especially in the small- to medium- enterprise segments of U.S. manufacturing*. These challenges are well researched and documented in various publications by the NIST, the Smart Manufacturing Leadership Consortium, and serve as the key reasons for the recent MTAC pilots and the Manufacturing Extension Partnership (MEP) program administered by NIST[8].

*A: Risk, Complexity and Initial Cost:* Since technical solutions are complex and interdependent, taking action on comprehensive 'horizontal' methodologies comes with a full gamut of investment, market, technology, legacy, security and organizational changes for manufacturers that will be felt across small, medium and large companies in different ways. Small and medium enterprises in particular face greater challenges in successfully navigating the risks associated with these changes.

*B: Rapid changes in technology:* While emerging technologies and models can drive cost down**,** complexity increases as new cloud technologies necessitate changes in data, information and modeling products, services and business models. Additionally, due to the interdependence of solutions, value chain access is hard for new entrants, inhibiting innovation and the ability to limit risks.

*C: Industry know how:* While many of the technologies encompassed by the ASCPM space are broad-based, the application is often industry or even entity-specific. This limits large investment by both technology vendors and potential manufacturers unless value can be demonstrated for the proposed new approaches.

*D: Workforce availability:* Due to complex and interdisciplinary nature of the technologies, workforce talent is limited. An investment in this area can lead to a significant national competitive advantage.

### *Technical Gaps and Challenges*

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[8] Connecting Small Manufacturers with the Capital Needed to Grow, Compete and Succeed: Small Manufacturers Inventory and Needs Assessment Report, November 2011, MEP, NIST.

The salient thematic technical challenges in this MTA are highlighted below and grouped in approximate order of their ability to be implemented. In doing so, it is acknowledged that research to address the more challenging gaps is also important and can bring substantial rewards to the nations that succeed in the effort. A more comprehensive list of the technical gaps is available as an annex to this report.

*Gap – 1: Open standards and interoperability for manufacturing devices, systems, and services*

Vendor lock-in is a widely acknowledged barrier to innovation in sensing, control, and platforms for manufacturing. Standardization of information and communication has been attempted but with limited success and slow outcomes. It should be noted that standards, even open standards, are not sufficient alone. Interoperability must also be assured.

*Gap – 2: Real-time measurement, monitoring and optimization solutions of machine energy consumption and waste streams*

In several manufacturing sectors, product quality, throughput, and plant efficiency suffer because of the lack of fast, noninvasive measurement methods. In many cases, samples must be analyzed or tested in a lab, or production must be affected for accurate measurement. Depending on the factory and process, noninvasive measurement could take different forms: stand-off imaging, disposable embedded sensors, inferential sensing, and others. In all cases reliable and cost-effective techniques are needed. These same technologies can be implemented for optimizing the energy consumption in a plant environment, for both continuous and discrete manufacturing processes.

*Gap – 3: Energy optimization of processes and integration with smart grids, cogeneration, and microgrids*

Dynamic energy optimization in industrial plants can improve manufacturing efficiency while simultaneously facilitating the integration of renewable generation in the grid. Affordable and accessible energy-holistic manufacturing simulation models will benefit design and operation. Choices of fuel/power use, generate or purchase decisions, integration of storage of different types, model-based optimization, can all be done vastly better than they are today, across a broader swath of the nation's manufacturing base.

*Gap – 4: Health management for manufacturing equipment and systems*

This gap includes needs such as fault diagnosis, detection of incipient problems, and condition-based and predictive maintenance. Techniques developed generally lack rigor and broad applicability. Here too sector-specific techniques will often be needed, but broad classes of equipment are deployed across many manufacturing sectors and can be targeted—e.g., pumps, fans, motors, burners, and furnaces. In addition to plant performance and efficiency, the safety of people and the environment are at stake.

*Gap – 5: Low-power, resilient wireless sensors and sensor networks*

A now long-standing promise of the wireless revolution has been pervasive sensing. Yet despite advances the promise remains well short of fulfillment. Encapsulating a radio with the transducer is not sufficient. Power management, possibly with energy harvesting, and reliable and fault-tolerant communication tied with the physical measurement is required—

and solutions must be robust to the manufacturing environment and work practices. Addressing these gaps is crucial.

*Gap – 6: Integration with Big Data Analytics and Digital Thread*

The technology areas referred to in this report are all data- and model-intensive. Advanced sensing, control, and platforms--and their integration--will produce vast amounts of data that can be mined for further models and simulations development; monitoring, control, and optimization techniques; and intelligent decision support systems. Sources of data are multifarious--weather forecasts, markets, plant historians, real-time process state and part quality data, equipment specifications, supply-chain databases, and others. Just as one example, the integration of energy storage technologies and the nascent efforts for using weather-based demand prediction for participating in energy markets present an opportunity to integrate Big Data analytics and digital thread technologies to the next level and embed decision support systems to make trade-off decisions on operations and asset utilization.

*Gap – 7: Platform infrastructure for integration and orchestration of public and private data and software across heterogeneous and human systems*

Cyber-physical platforms integrate computing and communication capabilities in the sensing and actuation functions of components. Public and private applications and data resources need to interconnect to achieve horizontal enterprise views and actions. Many data and information "seams" are not well bridged with existing systems and platform technologies. As the complexity of platform integration grows there is further need for methods to design and build platform infrastructures.

*Gap – 8: Software-service oriented platforms for manufacturing automation*

Manufacturing automation relies predominantly on single-vendor monolithic software architectures. Service architecture approaches can enable the extensive and systematic application of data analytics, models, and software innovations in physical manufacturing while recognizing cyber involvement. Such approaches will enable multiple development environments, infrastructures that support composability, and cloud-based orchestration. Appropriate cybersecurity considerations must be incorporated from the outset.

*Gap – 9: Theory and algorithms for model-based control and optimization in the manufacturing domain*

The model-based control and optimization paradigm is widely and successfully used in some manufacturing sectors but has had limited application in many others. Industry-specific aspects must be considered if useful tools and technologies are to be derived. Topics of interest include nonlinear, stochastic, and adaptive control; large-scale and enterprise-wide optimization; integration of planning, scheduling, and control; and co-design of manufacturing processes with sensing and control strategies.

*Gap – 10: Modeling and simulation at temporal and spatial scales relevant across manufacturing*

Models are at the core of many ASCPM technology gaps. Not only is an increasingly rich diversity of real-time and life-cycle modeling resources important, but also important are the tools and methods to more easily and cost-effectively build, deploy, and maintain models across large heterogeneous systems. Model alignment is also an outstanding need, especially since advanced manufacturing is dependent on models for various functions—e.g., planning, optimization, diagnostics, control.

### *The Case for a Public-Private Partnership*

While industrial automation is a >$60 B industry and several U.S. manufacturing sectors have benefited from advances in sensing and control over the last few decades, penetration of these technologies has not been widespread. In particular, U.S. small and medium enterprises have lagged behind larger organizations on productivity growth due in large part to the lack of adoption of such technologies. Beyond technology expertise, the implementation is impeded by lack of cost-effective IT platforms and infrastructure and other implementation gaps identified earlier. We believe that **public-private partnerships** are essential to accelerate the transformation of manufacturing by breaking out of compartmentalization and vertical optimization and by taking a comprehensive and integrated view of the role of data, information and models for agile, demand driven supply chains, plant wide optimization and sustainable production. *An assessment of the challenges stated above clearly elucidates that not only do the solutions not lie exclusively in the public or private domain, but a concerted, focused and systematic effort will be required to create a significant positive impact on the economy*. All our recommendations, therefore, call for participation and contributions of capabilities and/or financial resources by government, academia and private sector.

## Recommendations

The above technical and business implementation gaps lead us to recommend the following set of actions by a joint effort of the public and private sectors. More specifically, we recommend private institutions take a leadership role in adopting some of the recommendations and ensuring commercial viability of technology investments through such partnerships.

### *Recommendation I (Addresses Challenges/Gaps B, 1, 6, 7)*

We recommend that a national ASCPM Coordinating Committee be created under the auspices of NIST. This committee of experts from industry, academia and relevant government agencies should focus on the following deliverables:

a. Interoperability: Develop and implement interoperability standards and protocols for key systems with vendor support
b. Standards and Nomenclature: Develop and propose new methods for addressing relevant industry standards on an as needed, highly fast tracked basis working with key Standards Development Organizations
c. Technology road-mapping and development of a research agenda: Develop technology roadmaps and prioritize research investments with government

agencies on next generation sensors, process control and platform technologies in collaboration with relevant funding agencies (e.g. NSF, DOE, NASA, DOD, DARPA, NIST, etc.) and private sector participants to accelerate development

d. Coordinating Digital and Smart Manufacturing requirements: Digital design and Smart Manufacturing have distinct requirements that need to be integrated without losing appropriate emphasis on either.

***Recommendation II (Addresses Challenges/Gaps A, C, D, 2, 4, 5 & 8)***

We recommend that network of Smart Manufacturing Technology Testbeds (MTTs) be established with sector-focused demonstration and implementation capabilities that address the following needs. (Note: these MTTs should align with NNMI institutes as well as other centers and regional entities):

e. Focus on ASCPM needs and demands of industry/sectors
f. De-risk implementation of currently available technologies by providing physical and user centers virtual test beds for technology demonstration and evaluation
g. Provide ASCPM technology evaluation, development, demonstration, and customization services to small, medium, and large enterprises, in collaboration with vendors (for later stage TRL/MRL technologies)
h. Demonstrate the use of and potentially offer ‘platform’ services such as Manufacturing Software Cloud and demonstrate low-cost physical IT infrastructure for ASCPM technology evaluation and experimentation, demonstration, and training
i. Provide training and facilitation for technical and managerial staff by linking with industry and technical/community colleges
j. Coordinate with digital design and advanced materials centers, institutes and/or initiatives on common infrastructure and technologies so that the full life cycle of technology solutions are integrated at the point of demonstration and delivery.
k. Allow innovative approaches to solve industry problems by implementing new solutions as they emerge at other industry/academic/government research centers or NNMI institutes.

There are various models for these pilots such as: McKinsey’s Capability Center Network or DOE’s Manufacturing Demonstration Facility (MDF) and the Smart Manufacturing Leadership Coalition which operates with a combination of public and private contributions in the form of capabilities and financial resources. A possible modality to create these pilots is the MTAC program run by NIST. It is envisioned that these pilot centers will also leverage the SME outreach capabilities of NIST’s MEP program.

***Recommendation III (Addresses Challenges/Gaps A, 2, 3, 5, 6, 9 & 10)***

We recommend that a Clean Energy Manufacturing Innovation Institute be established, and led by DOE for energy intensive research, and development of ASPCM technologies in manufacturing operations that demonstrates and deliver technologies through the Network of Smart Manufacturing Centers. (This MTA is responsive to the recent DOE RFI.)

This institute should have the following objectives in order to overcome the gaps identified earlier.

- Accelerate the development and implementation of ASCPM technologies
- Sustain their integration into industry through the application of Smart and Digital Manufacturing modalities
- Serve as a test bed for emerging technologies and/or services pertinent to energy efficient manufacturing,
- Develop, demonstrate and facilitate the implementation of scalable market-driven models for the purpose of assisting public, private and non-profit energy intensive operations with decision-making.

## Conclusion

This report is based in part on more detailed gap assessments conducted by the ASCPM team. A separate report detailing these assessments is provided in Annex 2, and includes specialized reviews in three ASCPM subtopics—control and optimization, sensing and measurement, and platforms and frameworks.

# ANNEX 2

# TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 1 -

## *Advanced Sensing, Control, and Platforms for Manufacturing*

**Technical Gap Assessment in**

- **Control and Optimization,**
- **Sensing and Measurement, and**
- **Platforms and Frameworks**

Advanced Sensing, Controls, and Platforms for Manufacturing (ASCPM) technologies are strategically important for U.S. manufacturing: they offer the technical elements needed in digital and smart manufacturing to increase productivity, product and process agility, sustainability, and energy performance—and to thereby comprehensively improve the competitiveness of the nation's factories and fulfill the Administration's goals for advanced manufacturing.

To support the primary analysis of ASCPM in Annex 1, this letter report in Annex 2 summarizes technical gaps. It should be considered a companion to the primary ASCPM report in Annex 1, which includes, in addition to a consolidated gap summary, a discussion of nontechnical implementation barriers, a summary of current centers of expertise in each of the subareas, and recommendations for addressing the gaps and barriers.

## I. Methodology

A technical gap assessment was conducted by AMP2.0 within the Working Team-1 (Technology), with participation by a panel of experts from industry, academia, and government. Subteams were convened to delve into three subareas, respectively (1) sensing and measurement, (2) control and optimization, and (3) platforms and frameworks. These subareas overlap and many of the same experts took part in more than one subteam. Thus these efforts were coordinated and ultimately the outputs of each subteam were consolidated into a higher-level gap summary that is included in the master ASCPM letter report. At the same time, the technical gaps identified and discussed within each subarea are sufficiently specific to their disciplines to be worth documenting separately. Hence this report, which describes the subarea-specific gaps developed by the respective subteams. In most cases, the gaps are also rated on two dimensions:

- First, gap priorities are rated as low, medium, or high; these ratings should be interpreted as relative, qualitative assessments of the scale of impact on U.S. manufacturing that can be anticipated if a gap is successfully bridged.
- Second, the gap horizons—the time frame over which a gap is perceived to be addressable, with adequate investment—were evaluated as short-, medium-, or long-term. These horizons are defined as roughly up to 3 years, 3 – 7 years, and 7+ years.

The report also includes an appendix with names and contact information for the ASCPM team leaders, who can provide more details and background on the gap assessment, and the list of subject matter experts who participated in the undertaking.

## II. Sensing and Measurement Gaps

### Gap S-1: Sensors for bio-, nano-, and micro-manufacturing

Advanced sensors are needed for process control in emerging areas such as bio-, nano- and micro-manufacturing. Development of suitable sensing technologies for manufacturing processes in these emerging areas will enable integrated quality assurance, which is currently lacking in these new processes.

*This is a medium-to-high priority gap for the long-term. Advances in bio-, nano-, and micro-manufacturing will accelerate their industrial impact.*

Gap S-2: Non-invasive sensing and measurement solutions for advanced manufacturing

This gap addresses an important need, especially in discrete part manufacturing, where there is a critical need for cost-effective, non-invasive sensors that do not alter the physical characteristics of the machine and can directly measure the product characteristics to be controlled e.g. sensors for real-time *in-situ* measurement of surface and subsurface part quality in additive manufacturing and traditional processes. Formal methods for optimum sensor placement are also covered by this gap. Integration of such sensors into a machine/process will enable diagnostics and prognostics, condition based maintenance, and real-time process control and optimization.

*This is a high priority gap for the short-to-medium term and is expected to impact a wide range of traditional and emerging industry sectors.*

Gap S-3: Real-time process analyzers with multi-sensor data fusion capability

The vast amounts of time series data generated by in-line sensors have to be analyzed in real-time and converted to actionable information that can be fed to process monitoring, control, and optimization algorithms. This problem is compounded in complex manufacturing applications using multiple sensors, where there is a need for computationally-efficient data fusion algorithms that can simultaneously analyze multiple sensor data streams, rapidly identify process abnormalities, and initiate suitable control action.

*This is a high priority gap for the medium-term and is seen as a necessity for process improvement.*

Gap S-4: Wireless connectivity and self-contained power delivery/harvesting

Many sensors used in manufacturing today are physically wired to the data acquisition system. This limits the scalability of sensor installation and the ability to create spatially distributed sensor networks. By leveraging recent advances in low-cost wireless communication technologies, factory-level wireless sensor networks of all critical process parameters can be developed to enable sensor-to-sensor and/or sensor-to-controller communications. The lack of efficient, long-term, low-cost power sources and associated energy harvesting methods are also limiting the widespread implementation of wireless sensor networks.

*This is a high priority gap for the short-term. The durable power source/energy harvesting aspects may require a longer-term to address satisfactorily.*

Gap S-5: Knowledge-embedded smart sensor systems

This gap addresses the need for sensors with embedded knowledge that makes them smarter and easier to integrate into wired/wireless sensor networks employed in advanced manufacturing. Information about the sensor type, its measurement range, traceable calibration data, data conditioning and analysis algorithms, communication protocols, etc., can be embedded into the sensor system yielding a “plug-and-play” sensor. Some of this is possible through the addition of a memory device to the sensor, as discussed in the IEEE 1451 family of smart transducer interface standards. Adoption of the standards by sensor manufacturers is at an early stage and could be accelerated. Smart sensor systems will also facilitate self-calibration and self-checking of sensor accuracy, thereby enhancing the reliability and integrity of sensor data.

*This is a high priority gap for the short-to-medium term. Bridging the gap will promote greater integration of sensors into manufacturing processes while enhancing their accuracy, reliability, and trustworthiness.*

Gap S-6: Methods for managing sensor data uncertainty

Formal methods are needed for the quantification and management of measurement uncertainty associated with sensor data. Once developed, these methods will ensure the robustness of sensor data and will facilitate the development of effective process control strategies.

*This is a high priority gap for the short-to-medium term and bridging it will increase the robustness of information generated by sensors.*

Gap S-7: Standards for sensor calibration and measurement

While standards for primary calibration of certain sensor types are available (e.g. ASTM E1106 for Acoustic Emission Sensors), standards for measurement practice and calibration of other sensor types are lacking. Open standards will also facilitate interoperability of sensors and other ASCPM equipment and systems.

*This is a medium priority gap for the medium-to-long term. It is a desirable need that will eventually have to be addressed but is not viewed as critical for realizing stable control schemes.*

## III. Control and Optimization Gaps

Gap C-1: Theory and algorithms for control of fault-tolerant, stochastic, nonlinear, hybrid systems

There is a dearth of mathematical theory and computational implementations thereof that are sufficiently flexible and robust to deal with the complex nature of manufacturing plants and processes. Specific aspects of this complexity that must be considered include uncertainty, tolerance to equipment failures, and nonlinear and hybrid dynamics. There is a long history of research in control theory but the manufacturing domain has not in general been a target for this research. Continuous as well as hybrid discrete/continuous manufacturing processes will benefit if this gap is bridged.

*This is a high-priority gap with potential impact on U.S. manufacturing over the medium-to-long-term horizon. Addressing this gap will require focusing on the manufacturing domain and involving manufacturing experts in addition to control theorists.*

Gap C-2: Smart diagnostics, prognostics, and maintenance

Effective techniques for equipment and system health management will have tremendous impact on improving safety, plant efficiency and performance, and product quality and quantity. This gap includes needs such as fault diagnosis, detection of incipient problems, and condition-based and predictive maintenance. Also included is the "human-in-the-loop" element—e.g., decision support tools for operators and engineers. This has been a popular topic for applied research but most techniques developed lack rigor and broad applicability.

*This is a high-priority gap and significant impact on manufacturing can be attained in the short-to-medium term.*

Gap C-3: Human-in-the-loop monitoring and control

Many of the technical gaps for advanced manufacturing point to the need for better decision-support tools for plant personnel. In the control and optimization area, the "human-in-the-loop" element is incorporated within several of the high-priority gaps already considered. As a stand-alone gap the term is less a technical need and more of a generic operational requirement.

*Human-in-the-loop aspects are implicit in several other gaps. As a stand-alone technology gap, however, this is of relatively low priority.*

Gap C-4: Advanced control for discrete manufacturing

In principle, model-based control should be as relevant for discrete manufacturing as it is for continuous and batch processes—where numerous successful applications exist. In practice, the theory base for discrete manufacturing is not sufficiently well-developed today and will require significant research before broad-based applications can be considered. Sensors and other equipment in discrete manufacturing plants will also need to be enhanced in many cases.

*This is a low-priority gap for the short-term but in the long-term has the potential for large impact.*

Gap C-5: High-fidelity modeling and simulation for control and optimization

The integration of high-fidelity models and simulation within real-time control and optimization algorithms has long been a futuristic vision. Advances in high-performance computing and other information technology developments promise to make the vision a realizable proposition for significant-scale manufacturing problems in the now-foreseeable future. Modeling underpins virtually all advanced control and optimization capabilities.

*This is a high-priority gap that can be bridged in the medium-to-long term.*

Gap C-6: Integration of process control with planning and scheduling

As a result of the different temporal and spatial scales involved in planning, scheduling, and control in manufacturing facilities, different and compartmentalized tools are typically used for these critical functions. More seamless integration would enable factory operation at closer to the true optimum, greater agility in response to plant and market conditions, and other benefits. This gap is evident across the manufacturing spectrum, including for discrete manufacturing.

*This is a high-priority gap. Recent developments have shortened its horizon to the short-to-medium term.*

Gap C-7: Optimized co-design of process and sensing/control strategy

Sensor and actuator placement and the control strategy for a plant are crucial for manufacturing operation, but they are constrained by the design of the plant, which all-too-often is undertaken without taking them into account. A holistic design approach is possible, and for many applications the issue is not one of available technology but of engineering and management culture and the competing objectives of stakeholders.

*This is a medium-priority gap for greenfield plants and significant impact can be made in the short term.*

Gap C-8: Energy optimization with microgrids, smart grids, and cogeneration

The importance of energy optimization and integration in manufacturing is steadily increasing. Optimization can help match the economics and constraints of energy supplies and manufacturing facility operation. Automated demand response can bring economic benefits to all scales of manufacturing facilities (including small- and medium-scale enterprises). Microgrids and combined heat and power plants also offer opportunities, including for power export.

*This is a medium-priority gap for energy-intensive plants with near-term impact opportunities.*

## IV. Platform and Framework Gaps

A smart manufacturing platform is shared infrastructure that facilitates access and actionable enterprise application of real-time networked data and model-based analytics extensively throughout the business and the operation of the manufacturing enterprise. Smart platforms are also about the public-private infrastructure that no one company can build and still support public and private sector interests.

Gap P-1: IT infrastructure that facilitates enterprise-wide (1) integration of sensing, data and knowledge systems; (2) orchestration across heterogeneous systems; and (3) management of public and private applications and data

Data and knowledge systems built in one-off infrastructures do not leverage infrastructure costs and are dependent on individual developers, difficult to maintain as one-of-a-kind systems, not easily reused, and not easily integrated with other systems. Data and information "seams" arise as a result of heterogeneous groups of systems components that are not data-aligned and not effectively bridged with existing systems and control technologies. There is a need for a full range of public and private applications that can share data, public and private data that can share applications and applications that can connect to applications to achieve horizontal enterprise views and actions. Smart infrastructure needs to be interoperable; to accommodate public and proprietary information, open source, and commercial applications; and to deal with synchronicity of state and time between cyber and physical systems.

*Addressing this gap will require maintaining long-horizon goals while defining pathway steps that address all gaps as a comprehensive whole.*

Gap P-2: Standardized data models and information semantics for common interpretation and contextualization and standardized architectures for enterprise knowledge management

One of the most difficult but important technology gaps is the ability to condition, interpret, and contextualize data across heterogeneous systems or situations. There are critical needs for standardized information semantics across the manufacturing enterprise and/or ways to readily map and translate data without the increased complexity that comes with interface proliferation. Standardized decision workflows need to be orchestrated based on structured adaptation and autonomy across different time constants and seams, including the supply chain, without losing control of state. There is a need to execute across multi-vendor discrete, continuous, operational, and human/social structures and many different standards must be able to function consistently in overlapping domains. New rapid-development standards-based processes must account for industry needs, the providers of technology standards, vendors, and the subsequent adoption into vendor frameworks. Standards, however, cannot hold up progress with developing smart systems.

*This gap articulates the need for data models and a precise technical vocabulary, the need for standards that need to be developed in multi-layered ways in cyber-physical domains and platforms, and the need to use standards when available but not hold up implementation when they are not.*

Gap P-3: Smart infrastructure that aligns with and accommodates an increasingly rich and extensive (1) cyber involvement in all aspects of physical manufacturing, (2) range of software applications including open source and commercial, and (3) software development environment with a broadened developer base that is trending toward service-oriented IT architecture and infrastructure

Hardware is becoming more virtualized with configurability and application focused in the software. Software applications are already trending away from monolithic single-vendor integrated software solutions and toward service architecture approaches. Performance, agility, regulatory, and track and trace demands are increasing the need for on-time, in-production qualification of materials, multidimensional performance and adaptation, and cross-company operational data to improve enterprise performance. Low-cost, rugged, self-healing, wireless and information-fusing sensors need to be developed especially for *in situ*, in-production application of models. The development of models and simulations is a major challenge but an equally large challenge is the alignment of multiple models especially when developed for differing purposes—design, planning, optimization, maintenance, etc.

*In general this technology gap is high priority because software applications represent the essential cyber content that impact manufacturing. While smart platform infrastructure facilitates use and orchestration of software, software applications are needed to bring the infrastructure to life*

Gap P-4: As the complexity of platform integration grows there will be a need for methods to design and build platform infrastructures

Management of time and synchronization is a complex yet critical issue for real-time cyber physical systems (CPS). Human involvement is important while there is a need to preserve correctness in hybrid computer-human systems. There is a gap with cost-effective and secure system design, analysis, and construction methods for prototyping CPSs. Before making large investments in a prototype CPS, it is important for designers to create a model to understand the dynamics of the many subsystems and their interactions, including the environment in which the deployed system must operate. Approaches are needed to develop models that are robust and semantically precise, reduce design and verification costs, and are reusable assets. We can anticipate the need for methodologies to support designing for heterogeneity, interoperability, and compositionality. A core component of a platform is the interpretation of data from various sources. This leads to a need for structured processes to relate signals and symbols for inter-process and interpersonal communications.

*This overall collection of technology gaps in tools for designing and modeling platform infrastructure is long-horizon.*

### Gap P-5: Information, data, and IP security

Security in shared network infrastructures for manufacturing is so pervasive that it is called out as its own gap. For private, hybrid, and shared networks, the security of data, models, and information must be addressed at multiple layers. Additionally, public and private shared data, proprietary data and information, commercial and open-source model access, and marketplace data need to be managed under many possible policies and regulatory requirements.

# ANNEX 3

# TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 2 -

## *Visualization, Informatics, and Digital Manufacturing*

## Overview

The Advanced Manufacturing Partnership 2.0 (AMP2.0) provided recommendations in the full report to which this letter report is an annex. In that full report, AMP2.0 provided recommendations under the pillar of Enabling Innovation to strengthen manufacturing technology innovation. This effort included the process by which AMP2.0 identified Manufacturing Technology Areas (MTAs) of high national priority, as detailed in Appendix 1. Annexes 1-10 provide more detailed supporting information on the three MTAs that were prioritized via that AMP2.0 process. Annexes 1-2 focus on Advanced Sensing, Controls, and Platforms for Manufacturing (ASCPM); Annexes 3-6 focus on Visualization, Informatics, and Digital Manufacturing (VIDM), and Annexes 7-10 focus on Advanced Materials Manufacturing including three specific subsets. The recommendations for these three MTAs are summarized in Table 1 of the full report, and the process by which AMP2.0 developed these MTA analyses is described in Appendix 1.

Current technical gaps & challenges in our advanced manufacturing enterprise in the specific areas of **Visualization, Informatics, and Digital Manufacturing** areas, when addressed with the recommendations outlined subsequently, will increase the competitive advantage of U.S. manufacturing and job growth.

Rapid and widespread globalization over the past 25 years was primarily focused on leveraging competitive advantages from low cost, low skilled labor by using traditional manufacturing methods. This approach is now unsustainable due to key factors of the changing global environment such as:

- Recent advances in digital technologies,
- Labor inflation in emerging regions,
- The need for assured manufacturing,
- Product customization and personalization needs,
- Requirements for energy efficient operations,
- The demand for reduced lead times along with costs,
- The demand for increased agility, responsiveness, and resiliency across the supply chains end to end, and
- The drive for ubiquitous leverage and integration of information systems technologies in manufacturing

**Visualization, Informatics, & Digital Manufacturing (VIDM)** is a set of integrated, cross-cutting enterprise-level smart-manufacturing approaches, leveraging the current advances in information technology systems and tools that will improve U.S. manufacturing competitiveness through end-to-end supply-chain *efficiency*, unprecedented *flexibility,* and optimized energy management to achieve error-free manufacturing of customized products and components from digital designs, when needed and where needed.

The key drivers of VIDM are: *1) Increased R&D and manufacturing integration with end to end speed and productivity, supply chain efficiency, process yields, energy efficiency, improved sustainability; and 2) Improved process safety, flexibility, agility, configurability, and increased job satisfaction and pride.*

Currently less than 5% of industries use the full potential of VIDM. Within 5 years, ~50% of targeted industries such as Aerospace, Automotive, Chemical/Process Industries, and 90%

in 20 years may use VIDM tools and methodologies to achieve a 40-50%[9] reduction in product and manufacturing process development cycle times. VIDM will also enable a significant improvement in the ability of end-to-end supply chains to respond to market changes with improved flexibility and agility. The U.S. has natural technical strengths in VIDM as it remains the most advanced country for software development: 65 of the Global Top 100 Software Leaders are headquartered in the U.S. and they accounted for ~80% of the $243B software revenues in 2013. VIDM enables visualization of interconnected digital models and data using advanced tools across a heterogeneous multi-level cross-cutting supply chain – Plant level, Enterprise level, and cross-Enterprise level – and leverages Big Data analytics/simulations for effective decision making. This is accomplished through the backbone of a robust Cyber Security framework and High Speed Computing shared services infrastructure for U.S. Manufacturers to deliver optimum service levels (faster, cheaper, simpler, higher quality, energy efficient and more environmentally safe) to customers and consumers. This is depicted in the exhibit below where the digital thread within a plant, across plants and suppliers of an enterprise and across the plan, source, make, deliver and support value chains spread across diverse enterprises. The digital thread operates effectively when supported by integrated information systems providing right information and insights to right stake holders guiding right decision making.

Major participants defining the VIDM landscape are in the Aerospace, Automotive and the process industry with strong support from the IT industry. Major interest and drive are also coming from several federal agencies, including, the DOD, NIST, DOE, NASA, and NSF. There is an enormous stake in ensuring that U.S. Manufacturing, especially SMEs, evolves into a more agile, contemporary, connected, collaborative and efficient supply chain. The technology advances pioneered by the initial industry participants will be leveraged and expanded to other U.S. businesses and manufacturing industries over the next decade.

With this as the backdrop, our subsequent discussion on VIDM is focused into three sub-areas – namely, 1) *Digital Thread; 2) Integrated Information Systems; and 3) Manufacturing Big Data and Analytics*. The figure below clearly shows how these three sub-areas of focus need to mutually reinforce to accomplish the right level of advanced manufacturing technology driven competitiveness of U.S. manufacturing industry.

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[9] From Industry benchmark studies

## VISUALIZATION, INFORMATICS & DIGITAL MANUFACTURING

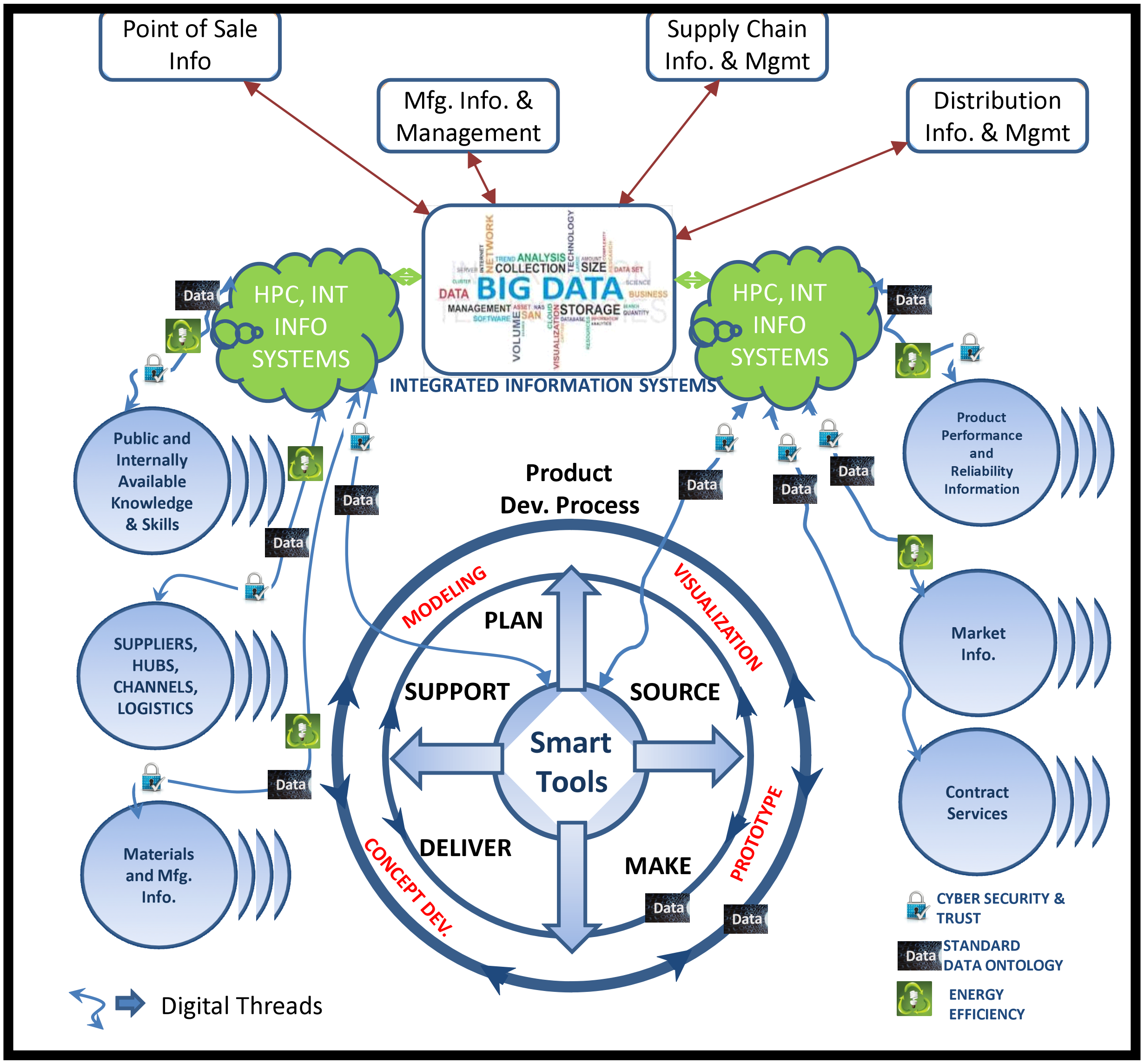
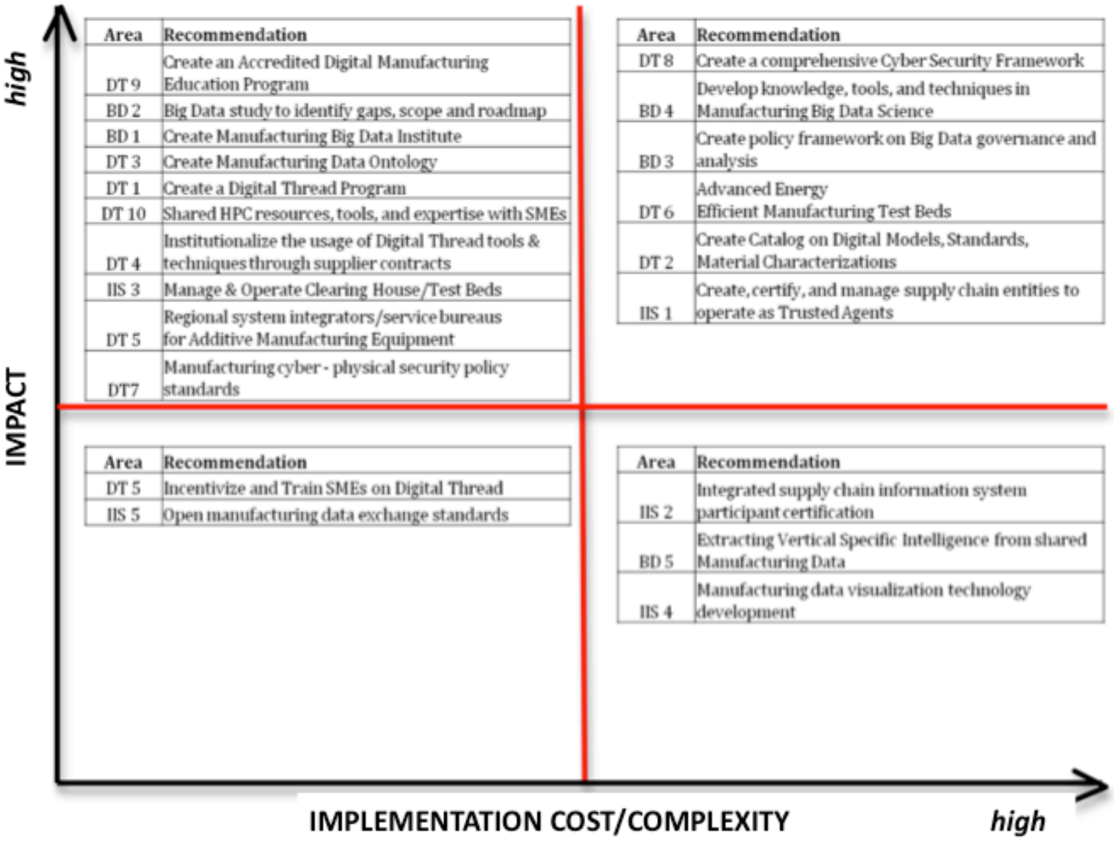


***Exhibit of:*** *Digital Thread, Big Data, and Integrated Information Systems across the supply chain at Plant level, Enterprise level, and x-Enterprise levels. This graphic illustrates the product development process as requiring smart tools from the planning to the delivery-of-product stages, indicating the need for standard data ontologies for secure and accurate data transferability; and the role of cyber security and trust to exchange such data within the supply network. The integrated information systems that enable this use of big data will impact manufacturing and supply chain management, point of sale exchanges, and product distribution. Advances in this use of the digital thread are also anticipated to enable increased energy efficiency at manufacturing facilities and across the supply network.*

Annexes 4-6 detail the technical gap analysis and recommendations for three specific components of VIDM: Digital Thread, Integrated Information Systems, and Big Data. Prioritized recommendations for the VIDM MTA on two dimensions are depicted below for easy reference:



| Area | Recommendation |
|---|---|
| DT 9 | Create an Accredited Digital Manufacturing Education Program |
| BD 2 | Big Data study to identify gaps, scope and roadmap |
| BD 1 | Create Manufacturing Big Data Institute |
| DT 3 | Create Manufacturing Data Ontology |
| DT 1 | Create a Digital Thread Program |
| DT 10 | Shared HPC resources, tools, and expertise with SMEs |
| DT 4 | Institutionalize the usage of Digital Thread tools & techniques through supplier contracts |
| IIS 3 | Manage & Operate Clearing House/Test Beds |
| DT 5 | Regional system integrators/service bureaus for Additive Manufacturing Equipment |
| DT7 | Manufacturing cyber - physical security policy standards |

| Area | Recommendation |
|---|---|
| DT 8 | Create a comprehensive Cyber Security Framework |
| BD 4 | Develop knowledge, tools, and techniques in Manufacturing Big Data Science |
| BD 3 | Create policy framework on Big Data governance and analysis |
| DT 6 | Advanced Energy Efficient Manufacturing Test Beds |
| DT 2 | Create Catalog on Digital Models, Standards, Material Characterizations |
| IIS 1 | Create, certify, and manage supply chain entities to operate as Trusted Agents |

| Area | Recommendation |
|---|---|
| DT 5 | Incentivize and Train SMEs on Digital Thread |
| IIS 5 | Open manufacturing data exchange standards |

| Area | Recommendation |
|---|---|
| IIS 2 | Integrated supply chain information system participant certification |
| BD 5 | Extracting Vertical Specific Intelligence from shared Manufacturing Data |
| IIS 4 | Manufacturing data visualization technology development |

**BD-**Big Data; **IIS-**Integrated Information Systems; **DT-**Digital

# ANNEX 4

# TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 2 -

## *Visualization, Information, and Digital Manufacturing*

## The Digital Thread

**The Digital Thread** integrates supply chain of data (from creation, conversion, extension, manipulation, transformation and utilization) that represents the evolution of a product throughout its lifecycle – from conception to manufacture and end-use, including maintenance services. A seamless digital thread provides the ability to interconnect, visualize, interpret, and optimize digital designs through integrated modeling of artifacts as the product's bill of materials (BOM) is digitally manufactured through additive manufacturing or used to digitally drive conventional manufacturing across the crosscutting multi-enterprise supply chain operations. It envisions a future where the design to manufacturing lead-time is substantially improved by utilizing advanced manufacturing technologies, high-fidelity Modeling & Simulation, and new human interaction modalities (e.g. virtual environments) to significantly reduce tool and fixture design, prototype development, and testing cycles. The manufactured artifacts will move directly from the conception and design stage, to modeling and analysis, to manufacturing, and to end-use product items in a seamless, assured, secure, energy efficient and error-free manner. Leveraging additive manufacturing will further accelerate end to end digital thread implementation and the full benefits of that. Many of the digital thread technology advances will immediately improve productivity in our manufacturing enterprises even before the digital thread is fully realized with advanced manufacturing including additive manufacturing.

An example of the digital design and digital manufacturing in the real world is TechShop[10]. For a fee; people are trained on digital modeling, given open access to design software, and make products individually or in collaboration with others – space and machines are provided. digital design and digital manufacturing are also evident through the enormous popularity of the *Maker Fairs* that showcase amazing projects, inventions, and remarkable stories of digital thread. While these examples are impactful, the digital thread practices are yet to manifest on a wide scale in the manufacturing enterprises, in both small and large scale on a comprehensive and systematic basis.

To fully realize and adopt the digital thread, our country needs technological advancements and support in areas such as high fidelity modeling and tooling; simulation & visualization; reliable & scalable cyber security; high performance computational support infrastructure; manufacturing data ontology; and Standards that can guide the collaborative evolution of breakthrough technologies. We have identified the following specific gaps and challenges that must be addressed to fully enable the digital thread across our manufacturing operations and supply-chains:

1. *Digital Models for Manufacturing:* Digital modeling using the existing technologies and analysis tools in Computer Aided Design (CAD), Computer Aided Engineering (CAE), Computer Aided Manufacturing (CAM), do not span functional or organizational boundaries and are often constrained by the limitations of vendor offerings and customization across multiple enterprise levels in the crosscutting supply chain. While these approaches build upon decades of data, protocols, handbooks, and product focused material and process characterizations, there is little support for sharing information and knowledge across the supply chain or

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[10] Techshop.ws – a business that leverages Digital Thread to manufacturing end-use items by providing access to tools, software, space, and training.

operations. To realize the productivity and economic benefits of the digital thread, these data and knowledge embodied in analysis tools must be readily available at the design time, early in the lifecycle with support for intellectual property protection. Without some level of standardization around the digital models and vendor and tool independence of these model data, advancement of digital thread will be limited.

2. *Advanced Digital Thread Tools:* CAD, CAM and CAE technologies and tools need to be further advanced with deeper analysis, simulation and modeling capabilities. These tools must be expanded or re-architected to allow designers to fully explore the design freedoms enabled by the digital thread. For example, a future analysis tool must allow designers to evaluate and visualize the evolution of a concept across the lifecycle, across multiple enterprise levels, and multiple levels of the supply chain. The tools should enable the various personas across the value chain to optimize the product, process and lifecycle impact of energy and environment to achieve multiple objectives at the same time. Such design freedoms and optimizations are likely to create a paradigm shift for our designers and move the advanced manufacturing agenda forward.
3. *Digital Manufacturing Data Ontology:* To guide capture, store, visualize, search and share both static and dynamic data in the digital thread across the end-to-end operations and supply chains, there is a need to formalize the data and transactions across the digital thread. There are different types of data that are created, as a product is conceptualized and moved into modeling and eventually to manufacture of end-use items; For example, *product data* (Specifications), *machine data* (to control and monitor manufacturing of the product), *design processes, manufacturing processes, supply chain data* (that impacts the quality, delivery and performance of the product), and *financial/cost data* associated with the changing market place and supply-chain as the product is being transformed from conception to reality. There needs to be standard nomenclature and semantics enabling seamless flow of digital thread data.
4. *Material Data Ontology:* Materials that are used for producing parts using digital thread either through conventional or additive manufacturing are not standardized or classified for full characterization of their properties. Lack of this material data ontology and standardization becomes a limiting factor for reducing the friction in institutionalizing digital thread. This gap needs to be addressed along with other material data standards related gaps identified in the advanced materials manufacturing technology area.
5. *Sharing and Trust Models for Digital Thread* – There is a lack of trust and protection to share digital models and data around these models across the cross-cutting supply chains because of IP issues, privacy, pricing, and the need for competitive distinction. To enable seamless interoperability and exchange of artifacts in the digital thread, there is an urgent need to decrease hesitation and increase trust across organizational and disciplinary boundaries. In addition to policy and business incentives, there is a need for new technologies for cross-disciplinary model verification. For example, can we promote and assure a manufacturing-plant's hydraulic system designer to reuse a digital model for a fuel pump developed and optimized by an automotive systems designer? Can we adequately mitigate safety and product stewardship concerns and transcend the technical-language barriers across such traditionally disparate design communities? Some aspects of Model Based Systems Engineering (MBSE) address a few of these issues. There is a need, however, for new models to create, personalize and customize digital models

of products, processes, and machines across the traditional supply-chain boundaries that focus on – digital model IP protection, data management, risk management, cyber security, design viability, and assured product manufacture and delivery in the digital thread.

6. *Digital Manufacturing Equipment and Materials:* Advanced manufacturing equipment is an area where not a lot of capability currently exists in the US. A similar situation is reoccurring now in the digital manufacturing area. For example, no independent US based company of significance exists today to provide metal additive manufacturing equipment to support the emerging additive manufacturing applications, especially in the aerospace, automotive, and chemical process industries. This gap, if unaddressed will create a competitive disadvantage to the U.S. manufacturing industry. Similarly, at this time, not many materials (ferrous & non-ferrous alloys) are qualified for products that can be made through additive manufacturing. The speed at which new materials are qualified will be a serious limiting factor for leveraging additive manufacturing for digital thread.
7. *Cyber Security Framework for Digital Thread:* To mitigate the vulnerabilities of highly sensitive digital data of products getting shared across value chain, there is a need for a comprehensive cyber security framework that spans the supply chain and the design, operation, and maintenance of the physical systems for manufacturing. This framework must include trustworthiness of machines and humans, and metrics informed validation of the framework. Advances such as the *'Internet of Things'* – that aim to provide massive sensor driven instrumentation of manufacturing supply chain further creates vulnerability for cyber attacks. There are no incentives for industry to share cyber threat information. There is no legislation or policy to protect companies that share threat information from liability. Sharing threat information across the end-to-end cross-cutting supply-chains may trigger legal anti-trust actions, and there is limited recognition of the unique attributes of manufacturing networks – for example, real-time performance, transactional architecture, potential to harm life or limb. Global cyber supply chains are the norm, and third party suppliers in the SME space are increasingly becoming vulnerable to cyber threats. The economic drivers for SMEs to participate in advanced manufacturing, exacerbates this issue, as SMEs are typically less likely to have the required key cyber security management capabilities.
8. *Scarcity of Talent for Digital Thread – Digital Design and Digital Manufacturing:* Experienced graduates and apprentices with inter-disciplinary skill sets are required to create, manage and sustain the digital thread. We need product technology domain specific training because there is emerging a critical need to change the academic perspective on advanced manufacturing with inter-disciplinary training combining manufacturing and information technologies. The manufacturing industry must also step up to share real world problems of right complexities and scale so the next generation of engineers can be better prepared to advance the manufacturing agenda. In addition, new tools and techniques are needed to capture and harness the experiential crosscutting knowledge that is very likely to be lost with our retiring workforce.
9. *High Performance Computing Platforms, Advanced tools, and Expertise:* There is a lack of awareness and expertise among SMEs of current capabilities of digital manufacturing technologies. For example in Smart/Digital materials manufacturing – SMEs often struggle to understand how to assess the applicability of these technologies to their operations and business needs. In addition, High Performance Computing (HPC) platforms and advanced digital thread tools in CAD, CAE and CAM

are typically prohibitive in cost, complexity and expertise required for SMEs to take full advantage of. Current network infrastructure impedes the ability of SMEs to analyze the data in real-time and effect operational changes. Also, data flow across HPC platforms and interfaces across the end-to-end supply chains are constrained by vendor limitations. Current license agreements are complex and expensive by the type and quantity of usage, location of the licensed software (floating vs. node-locked), and physical location of the end users and such other constraints and these will get in the way of SMEs effectively leveraging this software.

To accomplish the **Digital Thread (DT)**, we suggest implementation of the following recommendations:

DT 1 Incentivize innovative design, development and commercialization of knowledge, tools and techniques for the Digital Thread. Invest in technologies to support digital design (e.g., smart tools that can institutionalize knowledge reuse) and advanced manufacturing in connected and virtual environments.

- We recommend that NSF and other advanced research and development agencies in partnership with the private industry create a new crosscutting program around the Digital Thread, and allocate funding from multiple agencies to drive this program.

DT 2 Incentivize a university/industry partnership with NIST to set Digital manufacturing design standards, including cataloging data on strength of digitally manufactured materials, quality control protocols, along with full characterization of the material including time, cost and environmental effects.

DT 3 Incentivize the development of a supply chain-wide manufacturing data standards framework (including structure, content and ontology), through industry, SDOs and other public private partnership, that helps standardize the nomenclature and at the same time distinguishes between proprietary and non-proprietary data. Fund the identification, development and deployment of core data management technologies to store, collect, manage, analyze, and exchange large volumes of data – ensuring secure data storage and transmissions that can be used by U.S. firms both in-country and at their international facilities.

DT 4 We recommend that the Department of Defense mandate certain percentage of institutionalization of digital thread with advanced tools in pertinent vendor/supplier contracts to promote faster enabling and adoption of the Digital Thread by industry. We believe this will accelerate digital thread deployment.

DT 5 Initiate new efforts to:

- Incentivize, train and retrain U.S. SMEs to navigate the applicability of digital design and manufacturing technologies. For example – introduce additive manufacturing through locally administered community college and online learning programs for working professionals. Such a curriculum must also include modules to address organizational challenges, continuing education requirements for Professional Engineers (PEs) to successfully adopt such technologies.

- Incentivize through the pilot NNMI institutes on digital manufacturing and additive manufacturing, or other appropriate agencies creation and commercialization of additive manufacturing system integrators (distributed/regional service bureaus) for faster technology incorporation, and in addressing high volume requirements to enhance productivity, versus the current single point additive manufacturing solutions.

DT 6 Create a Department of Energy program to engage SMEs to offer new solutions for an energy efficient manufacturing infrastructure. For example, a nationally visible institute that hosts test beds for diverse applications which emphasizes energy management across multiple entities in the cross-cutting supply chains, along with agility, adaptability, and monitoring.

DT 7 Create policies incentivizing technologies, and practices (infrastructure) that offer protection from the Freedom of Information Act (FOIA) disclosures of threat information shared with the government and/or across the supply-chain. We urge you to drive a concentrated program to mitigate security risks at the interface of the cyber systems and physical equipment in the manufacturing ecosystem that is similar to the counterfeit protection program developed under the SAE G-19[11]. Elements of this program can be driven by standardization efforts led by NIST and by new research in cross-cutting programs such as the cyber physical systems programs at NSF with a renewed focus on digital design manufacturing and supply chain.

DT 8 Create a cross enterprise supply chain cyber security framework, leveraging the work going on at NIST on cyber security for smart manufacturing and similar work in other agencies to define the policy, practice and standards to protect companies from litigation, and improve the trust needed in assuring seamless digital thread implementation.

DT 9 Create nationally accredited programs on *Digital Manufacturing;* This initiative must be backed by incentives to connect degree programs across multiple levels – from associate degrees, to undergraduate degrees, and graduate degrees in interdisciplinary areas. The private industry and federal labs can be incentivized to support novel co-op and intern programs focused on creating talent for the Digital Thread. We recommend that the DMDI fund a university/industry partnership for a 12 month project to examine end-to-end advanced manufacturing education, technology and skill gaps and use the study results to formulate the proposed Digital Manufacturing program. Key focus areas commissioned by DMDI within this study could include: Data & Knowledge Science, Storage, Management and Analytics; Cyber Security; and Advanced Techniques to transcend traditional functional and disciplinary boundaries in manufacturing.

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[11] SAE is an international institution, and with the right team composition (Government Agencies, Industry, and University partnerships), a collaborative, multi-standard systems approach could be developed that would include an integrated, common test and metrics. To address the ad hoc barriers in the current state, this new proposed SAE standard would provide the means for common direction in technology roadmaps, integration of new innovations, robust sustainment, and rapid application.

DT 10 Deploy a federal cross-agency effort to incentivize private industry and universities to share high speed computing resources, software tools and expertise to advance the Digital Thread agenda. Key for this effort will be the availability of right expertise on a sustaining basis for SMEs to leverage using the business model of digital thread enablement as a service.

# ANNEX 5

## TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 2 -

## *Visualization, Information, and Digital Manufacturing*

## The Integrated Information Systems

**The Integrated Information Systems** envisions a future where knowledge, data and key attributes that affect the rapid manufacturing of digital designs are seamlessly exchanged and used by the supply-chain entities at multiple levels (manufacturers, customers, suppliers, distributors, hubs, channel partners etc.) with low or no friction to offer high quality and highly configurable products to customers. Integration of currently diverse and heterogeneous islands of information automation will reduce lead times, lower inventory costs, and proactively and enable quick visualization of issues and problems to make corrective and preventive interventions along with scenario based decision making. Such a connected enterprise and multi enterprise system will improve the U.S. manufacturing (large, small and medium enterprises) industry's offerings as well the efficiency and effectiveness of manufacturing of these offerings.

Currently, some of these capabilities are achieved using heterogeneous information systems with high level of company specific customizations creating enormous friction for seamless information flow and consequent information based decision making across crosscutting supply chains. In such systems, the level of configuration and custom development necessary to drive unified cross-enterprise agility and speed is prohibitive. Manufacturing enterprises use IT companies or functions to custom build adapters among the various information system islands of home-grown or packaged software applications for specific purposes creating barriers for quick evolution or flexible collaborative cross enterprise supply chain networks, while also increasing life cycle cost and time penalties. Lack of a proper cyber security framework across the supply chain, as covered in the digital thread, becomes a serious impediment to realizing effectively integrated manufacturing information systems. To enable full information, analytics and visualization based decision making by different disciplines required for digital manufacturing to become a reality, there is a need to integrate the current islands of information across the supply-chain, using open standards for data, processes and analysis. The future demands plug-n-play applications in contrast to the inflexible ERP, MES and other systems in a manufacturing enterprise. Such applications must seamlessly and securely interact with legacy systems using cloud based computing infrastructure to assure end-to-end supply-chain responsiveness and flexibility. With the significant current advantage we have in the U.S. with most of the software solutions used to enable digital thread or running manufacturing enterprises and supply chains being offered by U.S. based companies, we should be able to address this integrated information systems challenge to retain and increase this competitive advantage.

The Homeland Security's Global Entry program that is currently underway is an excellent example of an integrated information system enabler for digital thread, albeit with a few imperfections. This program allows expedited clearance for pre-approved, low-risk travelers and significantly reduces wait times and processing efficiencies. The key idea in this system is that entities who participate in the program are rigorously validated and certified; consequently, these entities are trusted agents and the processing efficiency is significantly improved for routine and repeated travel schedules. Lack of a similar system for rigorously validating and certifying manufacturing supply-chain entities and islands of information is a serious impediment to realization of digital thread and its benefits to improve U.S. manufacturing competitiveness.

Our country needs advancements in integrated information systems technology, standards, models, algorithms, as well as analytics and visualization approaches and methods to fully enable integrated information systems across crosscutting supply chains. The following key technical gaps and challenges need to be addressed on priority:

1. *Heterogeneous Systems, Infrastructure & Platforms:* Software systems and IT infrastructure across the islands of cross-cutting supply chains have different approaches and models for how they are designed and implemented that hinder the flow of information; this incompatibility makes it difficult to analyze non-local impact or exchange value creating information across the Digital Thread. Similarly, the platforms that are used for digital modeling and simulation vary among the supply chain entities. The current standards for data exchange today, such as ISO standard 10303 (STEP) and 14306 (JT file format), need to be extended to cover additional data structures and semantics to bridge the data, information and knowledge gaps across such software, hardware, and information systems infrastructure spread within and across enterprises.
2. *Real-time Analytics & Response Mechanisms:* Even when data are available from multiple streams of a crosscutting supply chain, the volume, variety and velocity of these data make it difficult to infer actionable intelligence and allow real time decisions to be made. Such intelligence is necessary to decrease the supply chain cycle times and inventory levels when fulfilling changing customer needs responsively. Further, in order to fully engage SMEs in the emerging advanced manufacturing landscape, it is necessary to offer services for analytics and response mechanisms on shared and accessible platforms for these SMEs to effectively participate in the digital thread. For example, an SME focused on supplying some materials as a part of the supply chain may benefit from timely process consultations and modification based on an analysis of the real-time data stream from the manufacturing stations; however, the current technologies limit the rates and types of the data which can be collected and consequently the utility of the analytics is also limited.
3. *Data Standards, Models & Algorithms:* In order to increase speed in the supply chain and manufacturing processes, large volumes of structured and unstructured data must be cleansed and harmonized to improve connectivity across crosscutting supply chain networks. We need scalable algorithms for processing, storing, visualizing, and analyzing such data in distributed databases and data streams. The lack of metadata, semantics, and relationships that are consistent with current manufacturing practices and industry standard supply-chain models such as SCOR[12] must be examined to improve connectivity between the supply-chain entities. There is also a lack of policies and methods to govern manufacturing data supply chain of generation, manipulation, sharing, conversion, and sun-setting across supply chain entities.
4. *Analytics and visualization software toolsets:* – There are no dominant advanced supply-chain analytics and visualization software toolsets driving the "network" to collaborate across the supply-chain entities. Analytics, and its subsequent effects of visualization for scenario based evaluation and decision making, to enable the crosscutting supply-chain for rapid responses are a big gap along with a need for semantically enabled ontology driven search engines and authoring tools to optimally support the seamless information exchanges between the islands of information throughout the supply-chain. Such tools must integrate heterogeneous information from multiple streams and allow designers and users to superpose

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[12] https://supply-chain.org/scor

knowledge from disparate domains to reduce the design to end-use lead-time and increase the ability to develop highly configurable offerings.

To address the above gaps, we recommend the following initiatives:

IIS 1 Create a Public/Private Agency to validate and certify supply chain entities to operate in Integrated Information Systems as trusted agents. This agency could design a suite of tests to validate interoperability and conformance to data standards and models and APIs in the digital thread. Such activities are very likely to result in predictable plug-n-play mechanisms in integrated information systems, without tracking or monitoring or attributing to any individual entity. Such an agency can actively promote collaboration between supply chain entities, emphasize participation by SMEs, and inform the formulation of data governance policies in a manner that is similar to the FDA and/or DEA.

IIS 2 Invest in the creation and management of a transparent process to certify supply chain entities to operate in integrated information systems and enabling digital thread. A rigorous and transparent process is very likely to promote trust and decrease cross-disciplinary friction to exchange digital models, meta-data, and knowledge across crosscutting supply chains.

IIS 3 Establish and operate community-wide test beds that include products, solutions and exploratory offerings from supply chain entities. These test beds will, among other activities, test and validate data exchange across end to end integrated supply chain entities, software systems and tools. Input for the design, operation and maintenance of these community-wide test beds needs to be done using a public solicitation process, incentivizing participation by SMEs to promote technology transfer and commercialization to nurture the advanced manufacturing ecosystem in the U.S.

IIS 4 Incentivize the development of technologies, algorithms, models and tools to visualize events and processes across crosscutting supply chains.

IIS 5 Support “Open Data policy” with robust data standards to permit the use of interoperable, transferable, useful data for analytics across the crosscutting supply chains, including mobile platforms.

# ANNEX 6

# TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 2 -

## *Visualization, Information, and Digital Manufacturing*

## Big Data

**Manufacturing Big Data, Visualization, and Analytics** envisions new knowledge, techniques, and tools to leverage all the data that is currently not exploited to distill actionable intelligence from this manufacturing data. These data must be collected and categorized from disparate systems, devices, networks, and humans using open meta-data standards. There is a need to enable new modalities for visualization and analytics that span the data collected or stored in various manufacturing and operations machinery and equipment as well as by various transaction-based applications and tools across crosscutting supply chains for more real time and agile decision making. These data must be linked appropriately with data in the Digital Thread that come from design, modeling, simulation, prototyping, testing as well as the non operational data like energy and product stewardship information to help digital thread and digital manufacturing to become a reality. Massive usage of sensors and instrumentation in manufacturing and supply chain operations will only increase the need for effective governance to effectively utilize the massive amounts of data. These massive amounts of data will need to be managed across the product life cycle with a superior data life cycle management system. Cyber security framework mentioned in the digital thread is essential to allow manufacturing big data and competitive advantage from that to become a reality.

Entities at different levels of crosscutting end-to-end supply chains – *Manufacturing Plants, Enterprises, and X-Enterprises* – have abundant unstructured data that are growing at unprecedented volumes, varieties and velocities. Without effective tools, these data cannot be transformed and distilled to actionable intelligence. While big data and its management are being addressed in many domains, manufacturing big data with its unique nature, scope and challenges need special attention to create competitive advantage for advanced manufacturing and digital thread.

Using SCOR[13] framework to build a framework for types and volumes of data and their management can be a great enabler to drive value from manufacturing big data for improving efficiency, agility, flexibility and effectiveness of manufacturing and supply chain operations. People of different disciplines use varying types and levels of data in the supply chain, to distill actionable intelligence to improve operations currently, though with a lot of human intervention and interpretation, which can be tedious and faulty. For example, one may find correlations from a set of machine data as a product evolves through a factory to improve the yields and throughput from a particular operation. A comprehensive storage, analysis and visualization of the data across crosscutting supply chains is likely to offer new insights into existing and next generation manufacturing processes. By distilling industry-vertical data, it is feasible to provide vertical specific operations and supply chain optimization insights.

Many federal agencies and private industries have made significant forays into Big Data. For example, DARPA's new Big Mechanism[14] program seeks the "Whys" hidden in Big Data. This program aims to leapfrog the state-of-the-art big data analytics by developing automated technologies to help explain the causes and effects that drive complicated systems. DARPA

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[13] https://supply-chain.org/our-frameworks

[14] DARPA's Big Mechanism program: http://www.darpa.mil/NewsEvents/Releases/2014/02/20.aspx.

also began the XDATA[15] program to develop computational techniques and software tools to enable large scale data processing in a wide range of potential settings, XDATA plans to release open-source software toolkits to enable collaboration among the applied mathematics, computer science and data visualization communities. We need to incentivize the reuse of such tools in the manufacturing domain, especially to increase the global competitiveness of US SMEs. We have identified the following key technical gaps and challenges to be addressed in leveraging manufacturing big data for competitive advantage:

1. “Big” in big data comes from dealing with large volumes of data characterized by volume, variety, velocity, veracity, and value. To successfully deploy and manage Big Data & its applications, we have to address the metadata management problem. Traditionally, the metadata defining this data is spread across the plants, and enterprises in spreadsheets, databases, applications, and even in people’s minds (e.g. tribal knowledge). Robust metadata management is not only necessary but required for successful information management. This is where we lack ontology-based reference models and manufacturing data models for effective data management throughout the product lifecycle.
2. There is a lack of trust in sharing and exchanging proprietary data across the enterprises, and no standard protocols are available to manage data security and privacy. Without this, opportunity to create competitive advantage through vertical specific optimization will not get realized.
3. There are different types of data (being created and used) across the end-to-end supply-chains – including product data (specifications), supply chain data (delivery, quality etc.), Financial/Cost data (product/service costs, value streams etc.). Given this data variety, in addition to the volumes and velocity; some of the challenges are; testing of Big Data for both structured and unstructured data validations; deploying scalable algorithms for processing unstructured data in distributed data systems across the supply-chains; using multidimensional extrapolation functions for automated analytics & decision making; and finally storing unprecedented volumes of current and accelerating data. Mining of this diverse data for specific, productive uses in an automated fashion needs significant improvement for effective, near real time decision making across operations and supply chain.
4. Visualization: Static charts (i.e. an X/Y graph without the ability to drill deeper) are not sufficient to leverage Big Data analytics. In addition there is a major gap in the fact that many cross-cutting supply chain entities use spreadsheets for too much of their data analysis. To effectively leverage Big Data across the supply-chain (manufacturing site levels, enterprise levels, and x-enterprise levels), there is a need to deploy flexible big data visualization – tables, graphs, maps, diagrams, charts, etc., which enables SMEs to create visualization dashboards to drive predictive analytics/simulations.

To address the above gaps, we recommend the following initiatives:

BD 1 Define the scope and establish a cross-agency manufacturing big data program. This program can be implemented as a cross agency manufacturing innovation institute,

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[15] DARPA’s XDATA program: http://www.darpa.mil/Our_Work/I2O/Programs/XDATA.aspx.

which complements but is distinct from an institute on digital manufacturing. This program can drive open standards for data, meta-data, and transactions to exchange these across crosscutting supply chains. It can also steer the evolution of open-source tools for representation, storage, and visualization of manufacturing big data, perhaps by redirecting existing assets in our universities, private industry and federal laboratories. Further, this program/institute can also host a sustained national discourse on manufacturing data science through workshops, conferences and tutorials.

BD 2 Task DMDI to conduct a university-industry partnership to study manufacturing big data. This study must focus on characterizing manufacturing big data, meta-data standards, data management, analysis and visualization tools, across the systems engineering lifecycle from design to end-use. It should also help identify the various ways of manufacturing data is wasted currently and how in different ways this data can be used to create business advantage. These activities are likely to result in a roadmap for manufacturing big data technology development and deployment. In addition, the output of this study can be leveraged to help define the appropriate scope and deliverables for the cross-agency manufacturing big data institute recommended in BD 1.

BD 3 Create national policies that address manufacturing big data governance and analysis, i.e., what data should belong to the manufacturing community and what should be protected for individual supply chain entities. This policy framework will need to also cover some type of certification and assurance abilities needed to allay the concerns and worries of companies about losing the privacy, competitive advantage embedded in their data through accidental or deliberate acts.

BD 4 Invest through various commercial and defense research agencies in the creation of new knowledge, techniques and tools in manufacturing big data science and manufacturing data ingress, egress, compressed storage, visualization, scenario evaluation and analytics related areas.

BD 5 Incentivize the extraction of industry-vertical specific intelligence from manufacturing big data for industry vertical competitive differentiation. This can be done through various competitions, events and reference model types of efforts.

# ANNEX 7

# TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 3 -

## *Advanced Materials Manufacturing*

## Overview

The Advanced Manufacturing Partnership 2.0 (AMP2.0) provided recommendations in the full report to which this letter report is an annex. In that full report, AMP2.0 provided recommendations under the pillar of Enabling Innovation to strengthen manufacturing technology innovation. This effort included the process by which AMP2.0 identified Manufacturing Technology Areas (MTAs) of high national priority, as detailed in Appendix 1. Annexes 1-10 provide more detailed supporting information on the three MTAs that were prioritized via that AMP2.0 process. Annexes 1-2 focus on Advanced Sensing, Controls, and Platforms for Manufacturing (ASCPM); Annexes 3-6 focus on Visualization, Informatics, and Digital Manufacturing (VIDM), and Annexes 7-10 focus on Advanced Materials Manufacturing including three specific subsets. The recommendations for these three MTAs are summarized in Table 1 of the full report, and the process by which AMP2.0 developed these MTA analyses is described in Appendix 1.

This letter summarizes the broad manufacturing technology area (MTA) termed **Advanced Materials Manufacturing**. Herein, we describe the motivational drivers, landscape of U.S. strengths and weaknesses, current technical gaps, and recommended actions including federal and public-private partnership investments that are required to close these gaps and thus achieve sustained U.S. strength in this key manufacturing technology area.

Annexes 8-10 provide three additional letters on specific **subsets of Advanced Materials Manufacturing (AMM)**. One of these subsets was announced during AMP2.0 as a topic for a new NNMI pilot institute (DOE Clean Energy Manufacturing Institute): **Advanced Structural Composites.** The other two AMM subsets, **Biomanufacturing** and **Critical Materials Reprocessing,** are of high national interest. Thus, Annex 7 first provides a general overview of materials manufacturing challenges within the U.S., and recommended actions that will serve to support and shape those three subset topics, as well as future such Advanced Materials Manufacturing topics and Institutes.

## Background

Advances in human use and invention of materials mark many other technological advances, as evidenced by associated progress in the Stone, Bronze, and Iron Ages. The capacity to manufacture those materials domestically is important for defense and strategic interests, including recent examples such as polymer production critical to space exploration and specialized metal production key to energy conversion devices. Materials design, synthesis, and processing have all advanced rapidly over the past decade, owing to both new computational predictive capabilities and new high-throughput fabrication and characterization methods. While many of these advances originated in the U.S., in some cases the U.S. has not maintained dominance or continued progress. Key drivers for U.S. strength in materials manufacturing derive from the:

- *Cross-cutting impact of materials innovation across multiple industries and sectors.* In many advanced technologies from consumer electronics to military sensors, materials of highly specific composition and microstructure actually enable the device performance. The material is the device, and a trained workforce to create and maintain those material-enabled devices is required for sustained innovation.
- *Historic national security and competitiveness implications of material supply uncertainty.* The capacity to produce and combine (join) materials with sufficient quantities and quality is required for sustainable innovation in several other

manufacturing technology areas. Disruptions of the global supply chain or insufficiency of a trained workforce can pause or halt other manufacturing sectors. Further, the "time to market" for scale-up and adoption of new or modified materials remains slow, typically on decadal time scales.

- *Potential to reduce burdens on natural resources associated with some materials manufacturing processes*. Synthesis of "new" materials with sufficient quality for industrial use can include processing of raw materials with impact on air, water, energy use, and land environments. Increased manufacturing production, while potentially beneficial from an economics and jobs perspective, can increase burdens on natural resources upon scale-up; such potentialities can be addressed by innovation in the materials manufacturing technologies.

Notably, the range of such materials (organic compounds, polymers, metals, semiconductors, ceramics, and composites thereof) varies so significantly that technical gaps and recommendations are better formulated in terms of specific material sets or scenarios. Thus, below we consider the shared features of the landscape and technical challenges in advanced materials manufacturing. AMP2.0 has prepared three additional letters, each analyzing one specific advanced materials manufacturing topic of particular importance to U.S. competitiveness: (1) advanced structural composites; and (2) biomanufacturing [of materials]; and (3) critical materials reprocessing. See the full report and Appendix 1 for drivers motivating analysis of manufacturing in these three areas; full analyses of each follow in Annexes 8-10. These three AMM subsets were selected in part due to shared challenges, technical breadth, and timely relationships to potential new federal agency investments including the National Network for Manufacturing Innovation (NNMI) institutes.

## Scope of Work

This topic was considered a singular Manufacturing Technology Area (MTA) within the PCAST AMP report. We hereafter term this broad topic as *Advanced Materials Manufacturing*, by which we mean advanced methods to design and produce a material of predictable and important functional properties within commercial products – regardless of whether that material is considered an "advanced material" such as a novel quantum dot, a "biomaterial" such as a therapeutic protein, or a "mature material" such as steel.

Current U.S. strengths in materials design are concentrated within academic institutions, most notably, in computational design ranging from the level of electronic/atomic structure to processed bulk structures; in industry most notably, in organic/polymeric materials and electronic materials; and in some federally funded laboratories, most notably, in initial scale-up and translation to products. Historic U.S. strengths in materials synthesis and processing vary by geographic region, linked typically to abundance of the required natural resources such as mineral ore, timber, hydrodynamic power, or to the historic co-location of the material end-user in a manufactured products like automobiles, paper goods and airplanes. For several reasons, high-volume processing of commodity materials has shifted to other nations. Qualification methodologies, including reliability testing of such materials, is not a U.S. educational focus; the lack of such shared data slows industry adoption of new materials and methods for safety-critical products in all sectors. Finally, current U.S. strengths in reprocessing of materials at the end-of-life stage of manufactured product lifecycle exist but are segmented by material or industry sector, and innovation in this area lags that of other nations.

## Key Findings

While advanced materials manufacturing has several common drivers, solutions to technical challenges differ widely for specific material classes and industry sectors. *Thus, we recommend sustained analysis of existing and emerging materials manufacturing scenarios by national experts within industry, academia, and government*. We have provided a list of U.S.-based subject matter experts that could identify additional, high-priority Advanced Materials Manufacturing scenarios. These experts are broadly knowledgeable of an array of materials manufacturing issues, opportunities, and international capabilities; they can serve as points of contact to identify specific subject matter experts in a given material scenario subset, as we have illustrated in the three Materials MTA subtopics analyzed during AMP2.0.

### Vision

Materials manufacturing in the U.S. must include continued excellence in materials design and invention, particularly at the lower technology readiness levels (TRL) 1-3 and manufacturing readiness levels (MRL) 3-5. However, a vision for U.S. strength in making and using those new or improved materials also requires increased prioritization of and investment in the technologies needed for the U.S. to make some of these materials at industrial production scales, at reasonable environmental impact levels, and within products designed to facilitate end-of-life recovery and reuse (for TRL/MRL4-9). This vision will enable U.S. to train a workforce that can invent, adapt, maintain, and recycle materials critical to U.S. infrastructure, defense, medical care, and quality-of-life. This vision will also accelerate the transition from lower to higher TRL/MRL maturity, to enable faster and broader industry adoption. Sustained execution of this vision will maintain a manufacturing environment within U.S. regions that spurs further innovation of new products via new uses of existing materials, as well as the necessary invention of new materials manufacturing methods to improve existing products.

### Technical Gaps & Implementation Challenges:

We list technical gaps and challenges for advanced materials manufacturing within several major categories. We have found these gaps to be persistent issues shared in common among many advanced materials manufacturing scenarios, although we emphasize that solutions are often sector-specific:

Standardization and qualification of materials properties:

> *Gap 1: Materials reliability qualification*: Adoption of new materials for existing products – especially safety-critical products such as load-bearing structures, transportation structures, defense assets – is extremely slow due to the pace and siloing of materials qualification data. Reliability engineering – which relies in part on such qualifications but also considers application of such materials in products under service conditions – is not a current U.S. strength in education or workforce training. Shared qualification methodologies, including the testing and prediction of material and product lifetimes, can accelerate the transition from manufactured prototypes to products. Such advances

may also enable changes in codes and material adoption policies that are composition-based instead of performance-based.

*Gap 2: Supply chain transparency*: Although industry places increasing priority on knowledge of existing supply chains, both materials suppliers and materials users can increase efficiency and lower cost by standardization of reporting, testing, and qualifications. This codified transparency and commonality of reporting tools are particularly important in tracking manufacturing changes for materials used in health- and safety-critical products. This may also help speed adoption and uptake of U.S.-manufactured novel materials, which is required to stem the tide of faltering, domestic small- and medium-manufacturers (SMMs) of materials due to investors' relative preference for SMMs of devices.

*Gap 3: Manufacturing-relevant material database*: Useful, validated database of materials structure and properties at industry-relevant conditions and specifications does not exist in ways that enable manufactured product design or end-of-life recovery and reuse. Industry sectors that rely increasingly on digital manufacturing of products stand to benefit greatly from access to such manufacturing-relevant data, even for mature materials.

Labor- and resource-intensive materials synthesis and processing:

Gap 4: *Environmental impact*: Many industrially relevant materials are processed with associated environmental impact on water quality, air quality, and land use. Alternative processing methods that can operate at scale could address this, enabling more materials processing steps along the complete supply chain to operate within the U.S.

Gap 5: *Automation-augmented processing*: Manual labor steps increasingly shift materials manufacturing to other nations. Increased automation of and skill required of this MTA could shift the balance in some materials sectors.

Gap 6: *Recovery of key materials*: Despite the associated cost of synthesis/processing new materials, there is scant innovation of and adoption of resource recovery, reuse, recycling, and reprocessing. Technological advances in this area could shift the U.S. supply curve with attendant workforce and environmental benefits, at competitive costs.

## Recommendations

We recommend that the following steps be taken to maintain and grow U.S. strength in advanced materials manufacturing, for a wide range of material types and uses.

### *Recommendation I*

The federal government should create a network of materials manufacturing centers of excellence (Materials MCEs), connected to several end-use manufacturers through physical proximity or virtual integration of the supply chain. This will provide the lower-TRL/MRL innovation required to feed the intellectual and technical pipeline of the National Network for Manufacturing Innovation (NNMI) institutes focused on specific materials and uses. These Materials MCEs can also address pressing cross-cutting materials manufacturing issues, including resource recovery and recycling. MCEs could be created under the auspices of existing, federally funded science and engineering center programs (e.g., NSF Engineering

Research Centers, DOE Energy Frontier Research Centers, and potentially DARPA) that would explicitly include a set of centers dedicated to closing specific technical gaps in advanced materials manufacturing.

### *Recommendation II*

The federal government should convene and maintain a group of materials manufacturing experts as part of a broader Advanced Manufacturing Advisory Consortium (AMAC), to advise the U.S. government on U.S. and international trends, technical challenges, and industrial opportunities in specific material classes and uses. The AMAC should provide a channel for private sector input, as was valuable during the AMP2.0 process that developed detailed MTA analyses. This AMAC component can assist and complement existing agency-specific boards like the Defense Science Board and National Academy panels via expertise in materials manufacturing viewed through a *national and public-private partnership lens that could include funding recommendations and industry perspective*, rather than an agency- or mission-specific lens. The AMAC component should include seasoned experts in materials scale-up and manufacturing from academia, industry, and federally funded laboratories. The AMAC component can annually identify Materials MTAs requiring "deep dive" analyses such as that illustrated by AMP2.0 for only three areas. Such sustained MMIB activity will help shape technology readiness level (1-3) funding priorities that would support progress in new areas, provide requisite basic research for existing NNMI Institutes at TRL/MRL 4-7, provide comment on whether NNMI Institute scoping is narrowed sufficiently for industry adoption, and identify potential new topics for public-private partnerships including but not limited to NNMI. This AMAC component of materials manufacturing experts can also serve an advisory role on development of potential workforce solutions including agency-funded Fellows programs that address industrial challenges with federal agency and laboratory expertise and access.

### *Recommendation III*

Public-private consortiums should establish sector-focused databases of materials composition-structure-property relations that are relevant to manufacturing and performance, with a focus on shared data ontology. These focused database consortium will endeavor to provide data in forms that are useful to industry at various stages of the supply chain and manufactured product lifecycle (including recovery and reprocessing potential; and reliability and lifecycle analysis) for a specific sector. This effort should include uniform data ontology standards (so that data could be shared among sectors as needed), and codified qualification and reliability results that map to supply chain-reporting requirements; NIST appears a natural home to lead and convene such data ontology standards codification. The new NNMI Lightweight and Modern Metals Manufacturing Innovation Institute may provide a useful and first sector-focused example, with the potential to develop such a database for lightweight structural metals in transportation applications. This approach may also help establish standardization of properties that can shift manufacturing to performance-based rather than composition-based metrics.

## *Drivers for analysis of three specific advanced materials manufacturing areas during AMP2.0*

As noted, Annexes 8-10 delineate three specific subsets of Advanced Materials Manufacturing. Below are the drivers motivating separate and detailed consideration of each of the following, given the broad possible coverage of materials manufacturing:

- Advanced Structural Composites Manufacturing
- Biomanufacturing [of therapeutic biologics]
- Critical Materials Reprocessing

### *Advanced Structural Composite Manufacturing*

High-strength, lightweight materials, within the context of a broad advanced composite materials framework, represent an area of current innovation for which the AMP2.0 effort can accelerate a sustainable competitive advantage for U.S. manufacturers. Structural composites typically include a continuous matrix (of polymers) with embedded fibers (of polymer, silicate glass, carbon, ceramic, or metal), and are intended to bear mechanical loads for extended duration without deforming permanently (creasing or breaking). Innovative manufacturing technologies can enable adoption of composite materials in an array of structural applications over the 5-year time horizon. This manufacturing advancement includes design of new processing, joining, and recycling methods that leverage both experimental and computational approaches; as well as new component materials, structures, and standardization approaches over longer time horizons. Specific drivers to support investment in this MTA include:

- *Cross-cutting supply chain.* Manufacturing technologies for lightweight, high-strength composites brings together polymer and multi-material fiber industries to provide raw materials in specific forms and at high volumes. Development of new equipment – or adaptation of manufacturing technologies to use current equipment – for production and assembly will be required to translate innovative composite components into commercial products at competitive throughput, cost, and quality. Last, but certainly not least, the properties of these materials will enable entirely new products with unparalleled performance.
- *Distributed manufacturing potential.* Composite manufacturing includes production of narrow fibers that are assembled into larger components, at the fiber production site or at other manufacturing locations. Joining, repair, and recycling of such composites remain outstanding technical challenges that will leverage workforce skills distinct from those currently held by metalworkers. This enables smaller shops across the U.S. to be competitive, creating a more diverse and disperse manufacturing base, as compared to the high-capital, high-temperature manufacturing of structural metals.
- *Lack of coordination between research and manufacturing.* U.S. leadership in university and government lab programs can drive innovative improvements across the life cycle. Computer technologies for design, testing and manufacturing improvements provide another source of competitive advantage that cuts across all markets. Adoption of advanced composites varies significantly among the aerospace, automotive, shipbuilding, construction, wind power, and biomedical device sectors. Performance requirements and manufacturing constraints vary widely by sector and transfer of knowledge across sectors is challenging. To be sure, manufacturing advancements in one sector can benefit another, but at higher technology readiness levels/manufacturing readiness levels (TRL/MRLs) the challenges are quite specific. There is an opportunity to identify the shared and sector-specific technical challenges that slow composite manufacturing advancement. Furthermore, addressing challenges common to all sectors can create a U.S. competitive advantage, leveraging materials and manufacturing innovation broadly.

### ***Biomanufacturing***

Biomanufacturing is a home-grown U.S. industry that remains deeply tied to basic research, is highly dependent on skilled labor, and is heavily regulated. However, competition from abroad, particularly among high labor-cost, high-skill countries has resulted in significant off-shore growth in the industry. As a result, there is concern that this high value-added industry will lose a foothold in the U.S., which raises concerns about critical issues of safety, quality and reproducibility, and supply chain availability. U.S. strength in biomanufacturing is uniquely impactful on human health, and to discovery of materials manufacturing methods with reduced environmental burden.

Biomanufacturing can be defined as the use of biology to produce known or new materials. This MTA can interpreted broadly to include the use of biological cells to synthesize or degrade specific compounds (e.g., therapeutic proteins, high-performance engine lubricants); the processing of compounds produced by nonhuman species that are then further processed to create new properties or functions (e.g., engineered silk proteins); the processing of biomass; synthetic biology and other topics that share few technical challenges in common.

A major focus of biomanufacturing is in the large-scale production of biologics (primarily but not exclusively therapeutic proteins such as antibodies and vaccines). Our AMP2.0 analysis focuses on this biomanufacturing topic, noting that others can be analyzed subsequently. Unlike many other industries where the fundamental science is highly advanced, biomanufacturing exploits what remains only a partial understanding of protein science, cell biology, bioprocess control, and biomedicine. For this reason, >80% of clinical production and >50% of commercial production of biologics occur within 100 miles of a company's R&D site. Such vertical integration remains an important differentiator of biomanufacturing vs. other industries. Moving biomanufacturing away from R&D in the U.S., therefore, can drive away key innovative advantages in biotechnology currently enjoyed by the U.S. This trend can result in the lower-quality production of biologics that are not safe for human health. This offshoring of biomanufacturing can also suppress U.S. innovation and the scale-up of new complex materials for non-medical applications.

Recently, two new paradigms in biomanufacturing have gained momentum. One involves "continuous biomanufacturing," wherein direct transition from pilot to commercial production occurs in a single facility, thereby necessitating a link between the R&D and commercial production. A second is on-demand biologics production, which is only now beginning and will satisfy the growing (and inevitable) need for more personalized medicine. The former will continue to enhance the vertically integrated nature of biomanufacturing. The latter may dramatically reshape the biomanufacturing landscape with immense ramifications for the U.S. pharmaceutical and biotechnology industries. For example, using largely disposable or "plug and play" biomanufacturing capabilities, it may be possible to generate small batches of biologics tailored to small populations (or even individuals) on a very short timescale. This will further drive the vertical integration from basic R&D (TRL1-3/MRL3-6), through pilot-scale production of engineered materials or of preclinical/clinical trials of therapeutic compounds. In addition, new regulations at the DOC and FDA (and foreign equivalents) will almost surely be developed to offer new regulatory requirements for engineered biological materials and for therapeutic biosimilars.

There is thus an emergent need to maintain existing and develop new biomanufacturing technologies in the U.S. to meet the growing challenge for safe, low cost next generation biologics and biologically complex materials. There is also the need to maintain the U.S. competitive advantage in high-end education (the industry remains largely driven at the R&D end by Ph.D. scientists) and in high-skill labor (e.g., through bachelor of science degrees and community college training).

### *Critical Materials Reprocessing*

Critical materials are those raw materials, typically elements or mineral ores, that are unstable in either supply or price, and which are necessary for technology development and deployment. An example of a critical material for national defense is molybdenum, a metallic element used in aircraft and space vehicle engine manufacturing, as well as in missile production [DOD 2013]. This material is also heavily used in civilian manufacturing of construction-grade steel, lightweight or high-temperature superalloys, and industrial lubricants. Importantly, critical materials are typically not "rare" in the sense of geological scarcity, and they are not necessarily expensive. However, these materials are not distributed uniformly throughout the Earth's crust, may be accessible in only specific geographic regions, and are often extracted using methods that do not meet U.S. environmental regulations. Because these critical materials can also be used in lower-tech or commercial products that can be of high or fluctuating demand (e.g., also used in consumer electronics, automotive platforms, industrial catalysts), any list naming materials that are "near-critical" is highly dynamic. Current reactions to materials criticality via stockpiling by government and by industry, sourcing from less developed or less stable nations, or speculation in domestic mining of "new" material sources can be highly disruptive to commercial manufacturing, as well as to defense and trade priorities [WTO 2014].

This manufacturing instability can be addressed by recovery and reprocessing of these critical material resources from existing products, with high potential for derivative benefits to materials manufacturing innovation. However, this "recycling" approach has received far less attention and investment. Specific drivers to support investment in this MTA include:

- *Clear technical challenges, with cross-cutting benefits.* Advanced recovery and reprocessing of critical materials includes several technical challenges, several of which relate to the electrochemical similarity among several elements and the high final purity required for reuse of these materials in new manufactured products. Manufacturing technologies that meet these challenges will also enable novel processing of raw materials (e.g., mineral ores), as well as the production of high-tech components designed with the full lifecycle in mind. Other technical challenges relate to high-rate recovery of materials from assembled products. These advances will result in more stable supply chains, resilient manufacturing bases with reduced risk of materials criticality, and the potential for domestic production of critical materials at volumes required for manufacturing scale-up.

- *Opportunity to complement federal investment in critical materials research:* Critical and strategic materials represent a longstanding manufacturing challenge (which, in the U.S., prompted the establishment of material stockpiles prior to WWII). In response to recent fluctuations and trade conflicts associated with so-called rare-earth metals, in 2013 the DOE EERE established a Critical Materials Institute (CMI) centered at Ames National Laboratory in Iowa. CMI is expected to address many topics related to supply and demand of materials considered critical to the DOE mission [DOE 2012], and thus will consider but not emphasize the multifaceted aspects of critical materials recovery and reprocessing with a broader national interest. AMP2.0 technical analysis and recommendations herein aim to leverage and complement that DOE investment of $120M over 5 years.
- *Significant opportunity to impact DOD manufacturing technologies and key assets.* Although critical materials in one industry sector can dramatically affect manufacturing progress in another, few industry sectors currently have sufficient knowledge of or control over supply chains to mitigate risk via reprocessing. The DOD is in a unique position to act as an innovative and cost-efficient test bed for materials recovering and reprocessing, in terms of both logistics [DLA 2013] and manufacturing technology. As but one example, DOD maintains control over retired airplane fleets that contain (literally) tons of critical materials; DOD also has a few specific examples of successful recovery and reprocessing of important materials within important technology platforms. This approach can both leverage existing assets that are rich in materials of interest, benefit develop of key assets that could use those materials, and drive down cost by implementing such manufacturing technologies at scale.

## **Conclusion**

The above assessment and recommendations are intended to serve as useful input for future federal and public-private partnership investments – of both time and funds – in the advanced materials manufacturing technologies and workforce.

# ANNEX 8

# TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 3 -

## *Advanced Materials Manufacturing*

## Structural Composites

Within the broad manufacturing technology area (MTA) termed **Advanced Materials Manufacturing**, we have identified three specific subtopics that are of current high national interest. Herein, for the Advanced Materials Manufacturing subset of ***Advanced Structural Composites Manufacturing***, we describe the motivational drivers, landscape of U.S. strengths and weaknesses, current technical gaps and implementation challenges, and recommended actions including federal and public-private partnership investments that are required to address these obstacles and thus achieve sustained U.S. strength in structural composites manufacturing. Note that AMP 2.0 was analyzing this materials manufacturing technology area prior to announcement of a National Network for Manufacturing Innovation (NNMI) pilot institute in advanced composites; our assessment and recommendations are made with this new development in mind.

## Background

Structural composite materials are currently in use at industrial scale, but with rather narrow applications due to high cost, limited joining methods with traditional material, low speed of manufacture, and certification and standards barriers. Composites are most widely used in the aerospace sector, yet the current certifiable methods for manufacture and use is state of the art circa 1990s – the last great U.S. effort to test, characterize and certify composite materials, manufacturing methods and international standards. This circumstance is a significant limiting factor to greater use of composites in industry for many applications. Creating the capability to support innovation, testing and certification will more quickly unlock the potential of composite materials in higher volume and everyday uses across society. High-strength, lightweight, corrosion resistant, and fatigue insensitive materials and structures within the context of a broad advanced composite materials framework, represent an area of current innovation for which the AMP2.0 recommendations can accelerate a sustainable competitive advantage for U.S. manufacturers. Structural composites typically include a continuous matrix with embedded fibers (of polymer, biofiber, glass, carbon, ceramic, or metal), and are intended to bear mechanical loads for extended duration without deforming permanently (creasing or breaking). Innovative manufacturing technologies can enable adoption of composite materials in an array of structural applications over the 5-year time horizon. This manufacturing advancement includes design of new processing, joining, and recycling methods that leverage both experimental and computational approaches; as well as new component materials, structures, and standardization approaches over longer time (decadal) horizons. Due to safety and durability requirements, a significant testing and certification effort is required to be able to use these materials for passenger and public safety applications. Specific drivers to support investment in this MTA are discussed in more detail in the Supplemental Information section, and include:

- *Cross-cutting supply chain.* Manufacturing technologies for lightweight, high-strength composites brings together polymer and multi-material fiber industries to provide raw materials in specific forms and at high volumes. Development of new equipment – or adaptation of manufacturing technologies to use current equipment – for production and assembly will be required to translate innovative composite components into commercial products at competitive throughput, cost, and quality. Last, but certainly not least, the properties of these materials will enable entirely new products with unparalleled performance.

- *Distributed manufacturing potential.* Composite manufacturing includes production of individual fibers and fiber preforms (e.g. strand, tows, tapes, fabrics) which can be dry or pre-impregnated with a matrix and which are assembled into larger components at the fiber production site or at other manufacturing locations. Joining, repair, and recycling of such composites remain outstanding technical challenges that will leverage workforce skills distinct from those currently held by metalworkers. This enables smaller shops across the U.S. to be competitive, creating a more diverse and disperse manufacturing base, as compared to the high-capital, high-temperature manufacturing of structural metals.
- *Lack of coordination between research and manufacturing.* U.S. leadership in university and government lab programs has proven unable to drive adoption in manufacturing. Focused application driven research has been lacking. Development of tools, such as computer technologies for design, testing and manufacturing improvements, have failed to create a competitive manufacturing advantage that cuts across all markets. Adoption of advanced composites varies significantly among the aerospace, automotive, shipbuilding, construction, wind power, and biomedical device sectors. Performance requirements and manufacturing constraints vary widely by sector and transfer of knowledge across sectors is challenging. To be sure, manufacturing advancements in one sector can benefit another, but at higher technology readiness levels/manufacturing readiness levels (TRL/MRLs) the challenges are quite specific. There is an opportunity to identify the shared and sector-specific technical challenges that slow composite manufacturing advancement. However, only through focused manufacturing efforts can the needle be moved. Broad efforts risk spreading efforts too thin. The challenge is to coordinate efforts to foster innovation, leveraging existing capabilities and while maintaining distinct efforts with clear focus.

## Scope of Work

Composites are already an active area of investigation across the academic, government and industrial landscape; however, a lack of access to large scale production quality machinery limits the ability to innovate and challenge existing uses and certification standards. Here, we highlight current and emergent U.S. activities including federally funded programs, industry-led efforts, and public-private consortia.

Adoption in aerospace has been broad, but adoption in automotive and structural applications has lagged. Higher volume applications are limited by a number of factors including material cost, cycle time during manufacturing, lack of automated assembly technology, and slow adoption rates due to regulation. However, well established supply chains exist for fiber reinforced composite component materials. These include organic, glass, PAN carbon fibers and nascent nanotube fibers, as well as the dominant thermoset matrix polymers or hybrid polymer matrix. Yet, current composite manufacturing technologies suffer from the slow production pace and the requirement for considerable manual intervention. Recycling is difficult, if not impossible, for components as fabricated today. Improvements across this spectrum are needed, including the commonly mentioned advancement toward thermoplastic matrices for both speed and recyclability.

Activities to foster growth range from industry sector-nonspecific efforts focused on the component materials development, to sector-specific consortia. *A major lesson gleaned from our analysis of structural composites manufacturing is that advances for one industry sector do not translate to success in another.* This landscape includes:

*Federally funded research, development, & deployment (RD&D):* Current U.S. activity includes federal (NSF, DOE, and DOD) programs, spanning from basic science (TRL 1-3 or 6.1/6.2 research) to development and deployment (TRL/MRL 4-7). Additional programs in 2014-2015 include anticipated DOD (DARPA) efforts that are distinct from the DOE-funded NNMI discussed in item 3 below. According to our analysis of current federal support of structural composites R&D, funds are concentrated chiefly at NSF (CMMI), DOD (ONR), and NASA, and are awarded chiefly to academic institutions.

*Public-private consortia:* There exist several consortia including federal agencies, academia, and/or industry sector members. These consortia focus on either a:

- *Single industry sector*: For example, NECST is the Nanoengineered Composite Aerospace Structures Consortium led by MIT with the University of Michigan, and partnered by companies including EADS/Airbus, Embraer, Lockheed Martin, Saab AB, Composite Systems Technology, Hexcel, and Toho Tenax. NECST focuses on early-stage development of carbon-nanotube/hybrid composite laminates that can be manufactured at quality, rate, and scale appropriate for full-scale aerospace structures.
- *Single component of structural composites*: For example, the DOE Oak Ridge Carbon Fiber Composites Consortium, led by Oak Ridge National Laboratory, was initiated in 2011 with 55 dues-paying members including companies (e.g., 3M, BASF, Cabot, Dow, UT-Battelle, Ford, GM, Volkswagen), four academic partners (Georgia Tech, Michigan State, Southern University, and Roane State Community College), and other nations' research institutions (e.g., Korea Institute for Carbon Convergence Technology). ORCFCC focuses on development and deployment of low cost carbon fiber composites, with an emphasis on low-cost production of long-length carbon fibers deployed in traditional fiber-reinforced thermoplastic resin composite laminates. It is aligned closely with the ORNL Carbon Fiber Technology Facility (CFTF), launched in 2009 by the DOE Vehicle Technologies Program to demonstrate semi-production level manufacturing of alternative carbon fiber precursors.
- *Single federal agency mission*: For example, DOD's The Composites Consortium (TCC) and Office of Naval Research (ONR) Composites Manufacturing Technology Center (CMTC) are managed by SCRA, and include 30 members such as defense contractors, weapons systems prime contractors, composites industry suppliers, small businesses and academic institutions. The stated focus of TCC and CMTC are composites manufacturing for DOD sea, land, and air defense applications.
- *Multi-application centers:* Several centers, like the University of Delaware Center for Composite Materials, founded in 1974, lists 47 member institutions that support its efforts across all facets of composite engineering. It is said to be the oldest continuously operating partnership focused on composites. It has been joined by others including the Advanced Structures and Composites Center at the University of Maine, founded in

2000; the National Composites Center in Kettering, OH, founded in 1996; and the Composite Materials & Engineering Center at Washington State. All are examples of public/private organizations that strive to broadly impact composite engineering. All involve a number of public and private entities in development and testing of composite structures for a variety of uses.

*Anticipated DOE-funded NNMI Institute:* Our initial analysis of structural composites pre-dated the February 2014 announcement of a new National Network for Manufacturing Innovation (NNMI) pilot institute, which is currently an active solicitation by DOE for a Clean Energy Manufacturing Institute, in Advanced Structural Composites. AMP2.0 has modified our MTA analysis to consider that NNMI focus in the context of the wider landscape of U.S. needs. The DOE NNMI Institute, according to the FOA and associated descriptions, will focus chiefly on reduced cost, high-rate production and increased energy efficiency in manufacturing of advanced fiber-reinforced polymer composites. The FOA excludes primary development of new materials and of an aerospace/aviation sector focus. Instead, this NNMI Institute will aim to advance manufacturing of existing materials at lowered cost, high-rate production and increased energy efficiency, and covers three distinct sectors: vehicles; wind power (turbine blades); and pressure vessels. Such focus by DOE can be useful, and naturally is not comprehensive for technical challenges across a wider range of industry sectors. Thus, our recommendations will address issues that are not anticipated to be addressed by this DOE NNMI Institute, as well as front-end and back-end investment required to sustain the aims of such an institute. Experts consulted openly question the wisdom of launching yet another effort in an area already well populated by industry/academic partnerships. The risk exists that without careful planning and coordination among existing and distinct efforts in structural composites manufacturing, the field will be spread thinner, rather than gaining focus on an application that can be moved forward.

### *Vision*

With appropriate investments and partnerships, we anticipate that advanced composite technologies will result in significant near-term benefits to the U.S. Within five years, by drawing on AMP2.0 analyses and recommendations, the U.S. would be recognized by manufacturing-intensive companies as the preeminent source of innovation in composites for a spectrum of applications. Those materials would be designed, manufactured, repaired, and recycled with U.S.-developed technology, and would benefit from distributed manufacturing throughout the U.S. in alignment with specific industry sector hubs. We will build on our strong aerospace technology and market base. We will push the performance of composite structures with the development of computational tools for variable stiffness structures, manufacturing technology for hybrid polymer solutions and assembly technology based on fusion bonding. Application of current and future aerospace technology will be extended into wider markets. Furthermore, advanced modeling efforts will ensure revolutionary new materials and structures continue to come to market and find new applications.

Beyond five years, the investments in biotechnology and computational science and engineering will further strengthen advanced material composites, and in particular processing and manufacturing of new composite materials and structures (see Appendix). From (bio)molecular and nano-scale components to macro-scale materials for ultimate commercial applications, there is a need to control composite architectures, direct assembly of nanostructured components, and synthesize novel polymeric and inorganic components that can be used in virtually all industrial applications from energy capture and storage to lightweight, high-strength fibers to biomedicine.

### ***Technical Gaps & Implementation Challenges***

Note that the above efforts have mostly focused on innovations to lower cost, through both materials change and faster production cycles. This approach leaves unaddressed several technical gaps required for U.S. manufacturing innovation strength and robust industry adoption. This assessment is based on publicly available assessments in the U.S. and internationally, and recognizes any previous gaps that have been addressed since the AMP report was issued. We group these gaps into three areas, with a more detailed discussion of those specific to carbon fiber-reinforced polymer composites in the Supplemental Information.

Gaps that are addressed and emphasized by DOE's mission specific NNMI FOA:

1. Sufficiently low cost production of carbon/glass fiber – advanced fiber-reinforced polymer composite parts for a few specific, non-aerospace, low-volume applications.
2. Sufficiently rapid production rates of carbon/glass fiber – advanced fiber-reinforced polymer composites for a few specific, non-aerospace, high-volume applications.

Gaps that are industry sector-agnostic, and not covered comprehensively by the DOE mission-specific NNMI FOA:

3. Recycling: End-of-use recovery and reprocessing technologies for structural composites are undeveloped, will be distinct from those established for structural metals, and require attention given the compositions and sizes of fibers and particles within such composites. While the topic is included within the DOE mission-specific NNMI FOA, an industry-emphasized goal suggests increased emphasis on this single gap through additional mechanisms across a wider range of composite types and industry sectors is desirable.
4. Inspection/Critical Flaw: Methods to develop design for manufacturing approaches that account for predetermined anomalies due to manufacturing and in service damage accumulation. These criteria will define appropriate inspection and monitoring methods required to guarantee designs meet industry performance standards.
5. Standards: Accepted standards and testing methods for composites and for the underlying raw materials do not exist or need significant refinement. Performance comparisons are difficult and slow adoption by any industry sector for any new product that has historically employed monolithic materials for which standards are mature.
6. Joining and bonding: Methods for metal joining are inappropriate, and current adhesive technologies exhibit insufficient performance for structural applications

such as for construction and for repair of complex structures. Includes aspects of workforce development due to unique skill set requirements and costs. Robust solutions have been developed for military applications. Bringing costs down and means to confirm reliability are likely required. Again, even if this topic is addressed in an NNMI Institute that focuses on other important goals such as cost and energy reduction, additional emphasis on joining/bonding innovation through other mechanisms can be highly complementary.

7. Limited fiber and matrix choices: The existing supply chain for fiber-reinforced polymer (FRP) structural composites consists of long-fiber producers, nascent nanotube or short-fiber producers, and polymer matrix producers. Fibers include conventional polyacrylonitrile (PAN)-based carbon fibers, carbon long-fibers produced from other precursors, glass fibers, and carbon nanotubes. Metallic, ceramic, and biological fibers should not be excluded from consideration since they provide superior functionality in some applications. Thermoset resins are dominant polymer matrices, yet transition to thermoplastic or hybrid polymer materials is widely heralded as a necessary advance for widespread adoption. Current thermoset manufacturing technologies suffer from the pace and requirement for considerable manual intervention. Improvements across this spectrum are needed. Regardless of the fiber or matrix, technical gaps persist at the interfaces between fibers and the polymer matrix within the composite, and at the interfaces between the composite and other materials comprising a functional structure. These are earlier-stage technical gaps than are expected to receive significant attention within an NNMI Institute.

Industry sector-specific challenges to rapid adoption:

8. Capital investment of component manufacturing: Mature, high-volume industry sectors have significant capital (billions USD) invested in current manufacturing equipment that cannot be used if composite materials are adopted to make the same structural components. For example, the automotive sector has developed and purchased industrial robotics and dedicated machines for metallic structures that are obsolete to current composite fiber laminates. Manufacturing technologies that can use or adapt existing capital equipment can speed adoption by such high-volume sectors.
9. Sector-specific process and performance specifications: Key manufacturing and performance metrics of structural composites vary widely among airplane fuselages, wind turbine blades, automotive frames, and prosthetic limbs, for example. Rather than iterative adaptations of long-fiber/thermoset manufacturing to fit square pegs within round holes, investments and partnerships that are highly sector-specific can speed creation and standardization of structural composite manufacturing that meets a sector's needs.

## Recommendations

Our recommendations to address the above technical gaps and implementation challenges include the following. These recommendations will be instrumental in addressing technical gaps within a 5-year time horizon for a specific industry sector (automotive) as a targeted example, as well as achieving the broader vision to revolutionize U.S. manufacturing of structural composites for diverse industry sectors.

### *Recommendation I (Addressing Gaps 4-7)*

*Establish a new public-private partnership consortium on standardization.* A standards program specifically for advanced structural composites is necessary to spur widespread adoption. Here, an automotive industry focused consortium has the advantages of mission relevance for multiple federal agencies (e.g., DOE, DOD including DARPA, NSF, DOC, DOL, DOT, and NIST), regionally distributed automotive suppliers and manufacturing locations, and a wide range of structural components with distinct manufacturing and performance requirements within a single finished product (the automobile). Focus on standards for structural composites used only as electric vehicle components is insufficient, though these will provide a useful reference point. This would complement rather than replace the recommendation in our *Advanced Materials Manufacturing* letter that the Lightweight and Modern Metals Manufacturing Innovation Institute serve as a pilot example case for material database standards and materials data ontology; in that case, the material subset is lightweight metals for transportation. The federal government should convene and partially fund such a consortium, and we suggest that NIST is a natural home to lead the federal effort.

### *Recommendation II (Addressing Gaps 1-2, 8-9)*

*Create incentives for sponsoring applications.* A specific manufacturing goal is likely necessary for success, gaged as significant industry adoption. One option to reduce risk in materials choice transitions for industry sectors is to adopt parts of the whole structure, providing real benefit while reducing risk [RMI, 2013]. A public-private consortium and incentive program focused on technical challenges of subassembly substitution offers a viable approach for increasing levels of composite adoption, especially in the automotive sector. A gradual replacement approach reduces redesign risks while still catalyzing change and can be used on all vehicles. In an automotive environment, replacement of wheels, rear cradles, battery shields, bumper beams, and suspension components can provide such an entry point. The federal government should fund such an incentive, partnered with industry experts sharing the risk in the specified subassembly substitution.

### *Recommendation III (Addressing Gaps 1-4, 6-7, 9)*

*Develop analytical and computational tools centered on composites.* Quality control of finished parts, detection of failure and confirmation of appropriate repair will be required for widespread adoption. Additionally, “design for manufacturing” practices must be developed to take best advantage of composites when replacing metallic or monolithic structures. Development and commercialization of such tools must be fostered to spur adoption within industry. Federal investment in R&D at low TRL/MRL levels through either Materials Manufacturing Centers of Excellence (Materials MCEs, see *Advanced Materials Manufacturing* Annex 7) or smaller grants to academia and/or small businesses would develop this pipeline required of wider industry adoption.

### *Recommendation IV (Addressing Gaps 3-4, 6, 9)*

*Invest in RD&D for structural composite joining, repair, and recycling.* Manufacturing of new structural composites at lower cost and higher throughput, as is addressed partially by the

DOE NNMI FOA, is only the first step in industrial adoption. The joining, repair, and recycling of structural composites must advance to the level of maturity held by metallic structures, and this will require new federal investment in basic research as well as continued industry investment in sector-specific RD&D. This could be achieved through dedicated Materials MCEs, or smaller grants to academia and/or small businesses. Such investment will be a necessary feed to composites-focused NNMI Institutes, as well as training grounds for a skilled workforce for assembly and repair in both civilian and defense contexts.

### *Recommendation V (Addressing Gaps 1-4, 6, 9)*

*Identify skill sets and establish training programs.* Currently used materials have established trainings and certification programs that will need to be duplicated for using radically new materials. Welding certification, as an analogy, will need to be replaced by a training and certification for joining, bonding, and structural composite damage detection and repair. Existing composite training programs can be leverage, and established training programs that exist for Aerospace, Marine (ABYC), Naval (U.S. Navy), and General Composites (ACMA) can be leveraged to wider audiences and modified for emerging applications. The skill sets and training program goals can be summarized by industry, and training programs can be established by leveraging and increasing public-private investment in the aforementioned programs, as well as nascent, public-private partnership apprenticeship pilot programs.

## ***SUPPLEMENTAL INFORMATION***

### *Long term impact of structural composite innovation*

In the longer term (20-year time horizon), we anticipate composites to truly revolutionize manufacturing of goods, vehicles and infrastructure. Examples [Eberle, 2013] include:

| | |
|---|---|
| Vehicle technologies | Necessary for >50% mass reduction to enable breakthrough vehicle efficiency |
| Wind energy | Needed for longer blade designs |
| Oil and gas | Offshore structural components resistant to corrosion and with superior mechanical performance |
| Pressurized gas storage | High specific strength to enable lighter tanks |
| Energy storage | Flywheels, batteries, capacitors |
| Power transmission | Less bulky structures, zero coefficient of linear thermal expansion |
| Nontraditional energy | Geothermal, solar, and ocean uses where resistance to corrosion and strength are needed |
| Civil infrastructure | Rapid repair and installation, time and cost savings in construction |
| Non-aerospace defense | Light weight, higher mobility |
| Aerospace | Continue to build on recognized strengths and expand to larger fraction of vehicle |
| Electronics | Light weight, EMI shielding |
| Thermal management | Thermal conductivity |
| Safety | Flameproof and superior strength |
| Filamentary sorbents | High specific surface area |

***Technical gaps and challenges*** that are specific to carbon fiber-reinforced polymer composites were summarized in a 2013 presentation by Warren and Eberle at ORNL [Warren 2013], and are listed here:

- *Materials Cost*: carbon fiber and resin cost currently price composites higher than metal for similar size applications. Costs will have to drop both on raw materials and processing for wide-spread acceptance in highest volume applications, and ultimately, cost in higher-value raw materials and processing capabilities will lead to wide-spread acceptance in increasingly smaller-volume applications.
- *Slow Manufacturing*: composite processing methods are currently hand intensive and slow. Hand lay-ups, laminations, weaving and pre-pegging all require time and add complexity. These must be transcended in favor of shorter cycle times and cost-optimized production.
- *Concern over Robustness (e.g., crash-worthiness for automotive materials)*: designers are not comfortable with and are not currently trained to use carbon fiber composites, especially in crash critical applications. The tendency of composites to

fail catastrophically (breaking) rather than via bending like metal leads to perceptions of weakness that do not exist in properly designed parts. Better design tools are needed and better experimental data in a range of applications.

- *Joining and Bonding:* workhorse methods like arc welding, resistive welding and thermal bonding do not work for composites. This leads to design complexity and assembly issues that must be overcome.
- *Sunk capital*: OEM's and suppliers in many industries have billions of dollars in capital investment already sunk into metal-based production equipment and facilities that are not yet ready for replacement. A capital build-out is required and is, at the same time hampered, by the ability of standing manufacturers to drop pricing in order to wring any remaining value from assets that are becoming obsolete.
- *Workforce Development:* existing workers require training to move to new materials of construction and bonding techniques.
- *Lack of Standards:* Standards for composites and for the underlying raw materials do not exist or need significant refinement. Performance comparisons are difficult and testing methods lagging. Small incorporation of out-of-spec material into a finished structure can create defects that are difficult to detect in the finished part making qualification of materials and fabrication technologies very important.
- *Lack of Assured Supply*: carbon fiber, compared to metals, is a small industry and has been rocked by supply and price disruptions. This causes concern throughout the supply chain and limits investment in parts manufacturing.
- *Repair:* repair is currently a metal-centric craft and damage is not immediately evident, frequently requiring new detection methods to confirm both defect and to validate repair. This is an area where naturally-inspired approaches, perhaps accelerated through computational design, can yield new routes to identification of defects/damage and autonomous repair mechanisms.
- *Resin Compatibility:* resin and fiber have to perform as a system and may not prove to be fully interchangeable since wetting and impregnation are key variables in determining the quality of the finished structure. Surface treatments and additive packages vary across vendors when commodity interchangeability is desired.
- *Recyclability:* recycling methods and the value of that recycle stream is uncertain.

***In addition to the aforementioned areas***, there is a current gap in the fundamental knowledge, tools, and techniques required to integrate biological molecules with nanostructured and polymeric synthetic materials to create functional and durable materials that can be processed and manufactured efficiently. Molecular/nanoscale materials will enable control of an entirely new "phase space" bounded by polymers, biomolecules, and nanoscale assemblies that must be explored to allow highly tunable functional material properties. At the intellectual core, there will be a need for better fundamental understanding of molecular interactions, structure, and function in largely unexplored regions of such nanocomposite composition space.

### *References*

Eberle 2013: Cliff Eberle, ORNL in "R&D on Low-Cost Carbon Fiber Composites for Energy Applications", presented at Carbon Fiber R&D Workshop, 25-26 July 2013.

RMI, 2013: The Rocky Mountain Institute, "KICKSTARTING THE WIDESPREAD ADOPTION OF AUTOMOTIVE CARBON FIBER COMPOSITES", a report on the Autocomposites Workshop Report, 2013.

Warren 2013: Dave Warren and Cliff Eberle of Oak Ridge National Laboratory in "Barriers to Widespread Adoption of Carbon Fibers in High Volume Applications", Presented to SAMTA, 28 February 2013.

# ANNEX 9

# TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 3 -

## *Advanced Materials Manufacturing*

## Biomanufacturing

Within the broad manufacturing technology area (MTA) termed **Advanced Materials Manufacturing**, we have identified three specific subtopics that are of current high national interest. Herein, for the Advanced Materials Manufacturing subset of ***Biomanufacturing*,** we describe the motivational drivers, landscape of U.S. strengths and weaknesses, current technical gaps and implementation challenges, and recommended actions including federal and public-private partnership investments that are required to address these obstacles and thus achieve sustained U.S. strength in one key component of biomanufacturing. Note that AMP 2.0 was analyzing this materials manufacturing technology area prior to announcement of any potential National Network for Manufacturing Innovation (NNMI) pilot institute in biomanufacturing were announced; our assessment and recommendations are made with this in mind.

## Background

Biomanufacturing is a home-grown U.S. industry that remains deeply tied to basic research, is highly dependent on skilled labor, and is heavily regulated. However, competition from abroad, particularly among high labor-cost, high-skill countries has resulted in significant offshore growth in the industry. As a result, there is concern that this high value-added industry will lose a foothold in the U.S., which currently represents $190 billion in annual domestic revenue. This potential shift raises concerns about critical issues of safety, quality and reproducibility, and supply chain availability. U.S. strength in biomanufacturing is uniquely impactful on human health, and to discovery of materials manufacturing methods with reduced environmental burden.

Biomanufacturing can be defined as the use of biology to produce known or new materials, as summarized in Table 1. This MTA can include use of biological cells to synthesize or degrade specific compounds (e.g., therapeutic proteins, high-performance engine lubricants), and it can include compounds produced by nonhuman species that are then further processed to create new properties or functions (e.g., engineered silk proteins). In our analysis, and to provide an initial focus on one core area of biomanufacturing, we have focused on manufacturing of biologics. Thus, other directions within biomanufacturing listed in Table 1 can be included in subsequent MTAs or letter reports that can lead to a series of public-private partnerships. These additional areas of biomanufacturing pose widely different technical challenges for development and production, and markedly different approaches for marketing and distribution.

Unlike many other industries for which the fundamental science is highly advanced, biomanufacturing of biologics exploits what remains only a partial understanding of protein science, cell biology, bioprocess control, and biomedicine. For this reason, >80% of clinical production and >50% of commercial production of biologics occur within 100 miles of a company's R&D site[16]. Such vertical integration remains an important differentiator of biomanufacturing vs. other industries. Moving biomanufacturing away from R&D in the U.S., therefore, can drive away key innovative advantages in biotechnology currently enjoyed by the U.S. This trend can result in the lower-quality production of biologics that are not safe

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[16] E.B. Reynolds (2011). The Changing Geography of Biomanufacturing. Industrial Performance Center, Massachusetts Institute of Technology.

for human health (e.g., <1% of an incorrectly glycosylated protein can be toxic in treatment of arthritis). This offshoring of biomanufacturing can also suppress U.S. innovation and scale-up of new complex materials for non-medical applications.

***Table 1. Broad Subsets of Biomanufacturing***

| Subset | Examples |
|---|---|
| **Biologics** | Therapeutic proteins, vaccines, heparins, etc. |
| **Cells and tissues, or components thereof** | Stem cell therapies, tissue engineering, etc. |
| **Biomaterials** | Bulk production of silk, cellulose, polyesters, lubricants, etc. |
| **Biomass processing** | Biofuels, value-added chemicals |
| **Synthetic biology and biocatalysis** | Synthesis of specialty and bulk chemicals & pharmaceuticals |
| | |

Recently, two new paradigms in biomanufacturing have gained momentum. One involves direct transition from pilot to commercial production, which occurs in a single facility and thus necessitates a link between the R&D and commercial production. Such an approach requires the co-location of high-end basic and applied research with highly integrated and controlled bioprocessing. A second trend is on-demand biologics production, which is only now beginning and will satisfy the growing (and inevitable) need for more personalized/precision medicine. The former will continue to enhance the vertically integrated nature of biomanufacturing. The latter may dramatically reshape the biomanufacturing landscape, with significant ramifications for the U.S. pharmaceutical and biotechnology industries. For example, using largely disposable or "plug and play" biomanufacturing capabilities, it may be possible to generate small batches of biologics tailored to small populations (or even individuals) on a very short timescale. This will further drive the vertical integration from basic R&D technology and manufacturing readiness levels (TRL1-3/MRL4-5), through pilot-scale production and preclinical/clinical trials of therapeutic compounds to commercial manufacturing (TRL4-9/MRL6-10). New processing routes and materials for biologics will drive the need for new regulatory approval requirements at the U.S. Food & Drug Administration (FDA) and foreign equivalents.

There is thus an emergent need to maintain existing and develop new biomanufacturing technologies in the U.S. to meet the growing challenge for safe, low cost next generation biologics and biologically complex materials. There is also the need to maintain the U.S. competitive advantage in high-end education (the industry remains largely driven at the R&D end by Ph.D. scientists) and in high-skill labor (e.g., through B.S. and community college training).

## Scope of Work

AMP2.0 has consulted U.S.-based experts and groups to provide feedback on the technical gaps and recommendations outlined in this letter report. The U.S. currently leads in developing and advancing the fundamental underpinnings of biomanufacturing, e.g., in mammalian cell culture, downstream processing, and analytic techniques, among others. However, the U.S. is not as proactive as it could be to leverage our strong national expertise and innovation in these underpinnings to grow U.S.-based production. Other industrialized and industrializing nations are more proactive in recruiting U.S.-led innovation and scientific advances to become leaders in biopharmaceutical production, including the development of national strategies, workforce training efforts from high-tech to skilled-labor levels, and tax incentives.

### *Vision*

Biomanufacturing of biologics in the U.S. is a critical short- and long-term need for the nation's manufacturing base, for both therapeutic and engineering materials. Accomplishments that would achieve this vision over a future five-year horizon include expansion of the vertically integrated supply chain/R&D platform that is necessary in transitioning from basic understanding of disease to therapeutic modalities; and in transitioning small-scale engineered protein production to industrial-scale quantities required of advanced composites and structures. Greater control of the chemical and biological equivalence in biosimilars as a function of manufacturing scale will be achieved, leading to more consistent, and safe, biologics. These advances will drive the FDA to re-evaluate biologic safety aspects through the advent of more high-end analytical techniques that can uncover undesirable protein glycosylation and other posttranslational modifications. Large-scale biologics production and the high degree of process control required will drive contract manufacturing firms to become more highly integrated with R&D operations. Finally, this specific component of biomanufacturing may adopt a public-private partnership similar to that of SEMATECH in the 1980s, including a consortium that identifies and addresses pre-competitive technical challenges.

In the longer term (10 to 20 years), biomanufacturing will move toward more continuous production and on-demand production, for biologics and the further development of materials and process control techniques that support advanced biologics manufacturing. This will revolutionize the pharmaceutical and biotechnology industries, and dramatically reshape scale from single products at metric ton scale per year to hundreds of products at 10s of grams scale per year at a single facility. This development will have profound implications on these industries, and engage federal regulatory agencies to adopt entirely new drug approval requirements or materials specifications, and impact healthcare.

## Key Findings

### *Technical Gaps & Implementation Challenges*

We list technical gaps and implementation challenges within several major categories directed toward biologics manufacturing.

*Biologics Production at Scale*

- ⇒ ***Gap 1***: Maintaining biologics quality as scale increases and requiring a deeper understanding for how to design processes to effectively manage the inevitable heterogeneity of biomanufactured product variants.
- ⇒ ***Gap 2***: Advanced on-line, real-time sensing and control over mammalian cell culture and protein products.
- ⇒ ***Gap 3***: Very high fidelity analytical techniques, identification of counterfeit biologics.
- ⇒ ***Gap 4***: Overcoming loss of product effectiveness for short half-life products.

*On-Demand Biologics*

- ⇒ ***Gap 5***: Development of rapid disposable bioprocess equipment and components in a continuous paradigm.
- ⇒ ***Gap 6***: Highly integrated bioprocessing on the small scale from upstream cell culture to downstream protein purification.
- ⇒ ***Gap 7***: Revamping of regulatory approval process to address potential for personalized medicine and for biology-based engineered materials. These include establishing new analytical standards for product variance and new routes to approvals of new process materials and approaches.

*Cross-Cutting Challenges*

- ⇒ ***Gap 8***: Continuous manufacturing building off other areas of manufacturing expertise.
- ⇒ ***Gap 9***: Conjugated biologics that consist of a biologic linked to a small molecule therapeutic that includes synthesis, purification, linker technology, and therapeutic delivery.
- ⇒ ***Gap 10***: Industry buy-in to a shared capabilities model, wherein intellectual property concerns are managed, particularly for industry-academia collaborations.

## Recommendations

The following recommendations address the above technical gaps and implementation challenges. These are intended to provide guidance to shared roles of the federal government, academic and trade institutions, and industry to advance biomanufacturing in the U.S. Each of these entities must work with the others synergistically, with precompetitive and early commercialization supported by the federal government with some industry buy-in via, for example, public-private partnerships, and more advanced commercialization stages driven largely by industry. This combination enables industry to contribute to long time-horizon, U.S.-based manufacturing technology innovation at a pre-competitive and collaborative level, while also achieving competitive advantages for specific products.

### *Recommendations to Addressing Gaps 1-6, 8-9*

*Develop advanced bioprocessing technologies, including mammalian cell genetics, cell culturing, on-line analytical techniques, and new biologically-compatible processing materials that can be employed to generate biologics at industrial scales.* Development of facilities and capabilities will be over-arching, and would ideally include an NNMI institute focused on this aspect of biomanufacturing, and also science-based manufacturing centers of excellence (MCEs) that could develop lower-TRL/MRL advances required to feed the innovation pipeline of the NNMI. These earlier stage R&D-based MCEs could be among the MCEs discussed in Annex 7 in the broad advanced materials manufacturing area, including dedication of a subset of existing research centers funded by NSF, DOE, NIH and others.

More broadly, noting that this letter report focuses on only one facet of biomanufacturing among those listed in Table 1, we recommend consideration to *establish several NNMI institutes in areas under the "biomanufacturing" umbrella defined in Table 1*. This consideration can be developed via workshops convened by the federal government in these areas, to identify those most suitable for such public-private consortium engagement. Note that these multiple biomanufacturing-focused NNMI institutes may constitute a network with some shared technical challenges, but that many technical, educational, regulatory, and industry sector issues are non-overlapping among these biomanufacturing areas.

The federal government should also convene and advertise a series of biomanufacturing workshops in areas defined in Table 1 to engage industry, academia, and government with the goal of defining clear steps for retaining U.S. prominence in biomanufacturing. These workshops can be co-hosted and co-organized by interested companies and by biomanufacturing industry associations (see Appendix). AMP2.0 has herein analyzed one such subset, and each will have some unique challenges and solutions. NSF held one such workshop related to biomaterials production in 2013, and USDA will reportedly hold one in 2014. However, the broad umbrella of biomanufacturing requires multiple analyses to identify commonalities and distinct challenges. The outcome of such workshops will be highly specific recommendations across the commercialization spectrum (from precompetitive to market) and in specific fields and product areas. Additional benefits will include interagency discussion and coordination of workshop topics, and the potential to gage and promote regional interests throughout the U.S.

### *Recommendation Addressing Gap 7*

*Reduce regulatory hurdles by creating a federal interagency working group that works with industry to streamline the regulatory process for biomanufacturing.* This includes obtaining more clarity from the FDA on new biomanufacturing approaches, particularly for small-scale, on-demand bioprocesses, and establishing more partnerships between biomanufacturers and regulators leading to more expedited reviews. Given that biomanufacturing is a key step in the translation of scientific findings that advance human health, increased engagement by NIH in such partnerships is recommended; other agencies including USDA and DOC should work with the FDA to proactively reduce such anticipated challenges to safe and economical U.S.-based manufacturing.

### *Recommendations to Address Gap 10*

*Initiate public-private partnerships for biomanufacturing*, in which pre-competitive technology sharing can be achieved for production scale-out (e.g., scale-up and scale-down), product diversity, process/safety monitoring in real-time, and quality by design. This includes investment of federal funds to initiate the initial infrastructure (e.g., space and people), within rapid transition toward a funding model of industry-supported pre-competitive research projects.

*Provide federal and state incentives for U.S. biomanufacturing industries*; the pharmaceutical industry has shown repeatedly and recently how small changes in tax structure or R&D credits attract manufacturing. Incentives must be put into place to make sure manufacturing of U.S. discoveries occurs in the U.S.

### *Recommendations to Address cross-cutting gaps*

*Private-public partnerships must assure future pools of properly trained bioprocess engineers be educated in the U.S.* The U.S. training of individuals in bioprocessing, over the spectrum of academic degree levels, is in jeopardy. In contrast to the E.U., which has provided significant funding for bioprocess engineering research and training, the U.S. funding in this area is minimal. In addition, the number of faculty training students in bioprocessing is small and consists primarily of senior faculty approaching retirement. Appropriate funding mechanisms and initiatives must be instituted, and can include direct industry (or consortium) sponsorship as well as federal incentives such as NIH-sponsored training grants.

*The Administration should task a federal agency, e.g., within NIST AMNPO or a biomanufacturing office within NIH or NSF, to track the U.S. biomanufacturing sector*, which represents a >$100B area of high growth.

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U.S. Congressional Briefing (Nov. 5, 2013)

# ANNEX 10

## TRANSFORMATIVE MANUFACTURING TECHNOLOGY:

## Manufacturing Technology Area 3 -

## *Advanced Materials Manufacturing*

## Critical Materials Reprocessing

Within the broad manufacturing technology area (MTA) termed **Advanced Materials Manufacturing**, we have identified three specific subtopics that are of current high national interest. Herein, for the Advanced Materials Manufacturing subset of ***Critical Materials Reprocessing*,** we describe the motivational drivers, landscape of U.S. strengths and weaknesses, current technical gaps and implementation challenges, and recommended actions including federal and public-private partnership investments that are required to address these obstacles and thus achieve sustained U.S. strength in this manufacturing topic of high national security implications. Note that AMP 2.0 was analyzing this materials manufacturing technology area prior to announcement of any potential National Network of Manufacturing Innovation (NNMI) Institutes in critical materials reprocessing were announced; our assessment and recommendations are made with this in mind.

## Background

Critical materials are those raw materials (typically elements or mineral ores) that are unstable in either supply or price, and which are necessary for technology development and deployment. An example of a critical material for national defense is molybdenum, a metallic element used in aircraft and space vehicle engine manufacturing, as well as in missile production [DOD 2013]. This material is also heavily used in civilian manufacturing of construction-grade steel, lightweight superalloys, and industrial lubricants. Importantly, critical materials are typically not "rare" in the sense of geological scarcity, and they are not necessarily expensive. These materials are also not necessarily and not limited to "confict minerals" under current lists and definitions [HES 2012], though critical materials are often characterized by geopolitical conflict due to unstable supply in the face of sustained demand. These materials are not distributed uniformly throughout the Earth's crust, may be accessible in only specific geographic regions, and are often extracted using methods that do not meet U.S. environmental regulations. Because these critical materials can also be used in lower-tech or commercial products that can be of high or fluctuating demand (e.g., also used in consumer electronics, automotive platforms, industrial catalysts), any list naming materials that are "near-critical" is highly dynamic. Current reactions to materials criticality via stockpiling by government and by industry, sourcing from less developed or less stable nations, or speculation in domestic mining of "new" material sources can be highly disruptive to commercial manufacturing, as well as to defense and trade priorities [WTO 2014].

There are several approaches that nations or industry can take to mitigate this risk; some of the options available to governments differ from those available to the industrial supply chain due to both policy and capital requirements. Concurrently, as the materials categorized as critical are dynamic and also perspective specific, varying with time and also varying among federal agencies and among manufacturing industry sectors, there is an interest in proactively identifying materials that are near-critical for a given sector. The criticality risk mitigation options include stockpiling of specific materials required of production, reduction or replacement of materials within manufactured components, increased supply through new mining and ore separations, and recycling of manufactured components by recovering and reprocessing specific materials [DOD 2013, DOE 2011]. This manufacturing instability can be addressed significantly by this last option – recovery and reprocessing of these critical material resources from existing products – with high potential for derivative benefits to materials manufacturing innovation. However, this "recycling" approach has received far less attention and investment. Specific drivers to support investment in this MTA include:

- *Clear technical challenges, with cross-cutting benefits.* Advanced recovery and reprocessing of critical materials includes several technical challenges, several of which relate to the electrochemical similarity among several elements and the high final purity required for reuse of these materials in new manufactured products. Manufacturing technologies that meet these challenges will also enable novel processing of raw materials (e.g., mineral ores), as well as the production of high-tech components designed with the full lifecycle in mind. Other technical challenges relate to high-rate recovery of materials from assembled products. These advances will result in more stable supply chains, resilient manufacturing bases with reduced risk of materials criticality, and the potential for domestic production of critical materials at volumes required for manufacturing scale-up.
- *Opportunity to complement federal investment in critical materials research:* Critical and strategic materials represent a longstanding manufacturing challenge (which, in the U.S., prompted the establishment of material stockpiles prior to WWII). In response to recent fluctuations and trade conflicts associated with so-called rare-earth metals, in 2013 the DOE EERE established a Critical Materials Institute (CMI) located at Ames National Laboratory in Iowa. CMI is expected to address many topics related to supply and demand of materials considered critical to the DOE mission [DOE 2012], and thus will consider but not emphasize the multifaceted aspects of critical materials recovery and reprocessing with a broader national interest. AMP2.0 technical analysis and recommendations herein aim to leverage and complement that DOE investment of $120M over 5 years.
- *Significant opportunity to impact DOD manufacturing technologies and key assets.* Although critical materials in one industry sector can dramatically affect manufacturing progress in another, few industry sectors currently have sufficient knowledge of or control over supply chains to mitigate risk via reprocessing. The DOD is in a unique position to act as an innovative and cost-efficient testbed for materials recovering and reprocessing, in terms of both logistics [DLA 2013] and manufacturing technology. As but one example, DOD maintains control over retired airplane fleets that contain (literally) tons of critical materials; DOD also has a few specific examples of successful recovery and reprocessing of important materials within important technology platforms. This approach can both leverage existing assets that are rich in materials of interest, benefit develop of key assets that could use those materials, and drive down cost by implementing such manufacturing technologies at scale.

## Scope of Work

AMP2.0 has consulted U.S.-based experts and groups to provide feedback on the technical gaps and recommendations outlined in this letter report.

Critical materials manufacturing exhibits an increasingly international footprint – ranging from start-of-life phases (extraction and processing of raw materials) to end-of-life phases (recycling from devices containing these materials in alloyed, thin film, or bulk form). Due in part to the defense-related uses of some of these materials, there is little international cooperation on technical issues. The U.S. and E.U. generally communicate regarding trade policy implications and basic research findings presented at technical conferences. Within the U.S., several multinational and domestic small-midsize enterprises (SMEs) are well distributed geographically, with concentrated activity in the mineral-rich West Coast and Rocky Mountain Corridor; several U.S. national laboratories include longstanding expertise in processing of such materials at high volumes and purities. However, workforce education and training (at all degree levels) is minimal nationwide. This U.S. trend in workforce education and training is in strong contrast with China [WTO 2014], which currently has invested in extensive RD&D, workforce training, and manufacturing capabilities for several currently critical materials; that nation has also increasingly expanded mining and extraction operations to nations in Africa and South America, often employing a trained workforce from China rather than from the local population. As compared to the United States, U.S. allies within the E.U., Canada, and Australia offer comparatively more education and training, due in part to local industry demand.

Specific to critical materials recovery and reprocessing, the U.S. expertise includes several academic and national laboratories, public-private consortia, and companies [LOS 2012]. Additionally, DOE launched in 2013 a Critical Materials Institute as one of the DOE Energy Innovation Hubs, which will include some activity in recycling of elements considered currently critical by that federal agency's Critical Materials Strategy [DOE 2012].

### *Vision*

The AMP2.0 recommendations below are intended to produce impact on U.S. manufacturing strength for critical materials reprocessing within five years (short-term) and twenty years (long-term). Within five years, the U.S. will establish leadership in industrial-scale Advanced Recovery & Reprocessing Technology (ARRT) for elements considered currently or nearly critical from a DoD or whole-government perspective. The U.S. will demonstrate critical materials recovery and reprocessing from current defense assets, suitable for use in new commercial products, in new military assets, or as certified stockpile resources. By developing this capability through the high-volume DoD supply chain, the logistics and costs associated with critical materials reprocessing will be reduced sufficiently to enable widespread adoption in civilian industries over the next decade. Within 20 years, ARRT will have transformed "design for manufacturing" to include facile recovery of key materials for subsequent reuse in the same or other products; will have enabled processing of raw materials with reduced environmental impact; and will have created generations of U.S. researchers, workforces, companies, and federal agencies that consider the complete materials lifecycle in manufacturing innovation. This vision informs the technical gaps that must be overcome and the recommendations of public and private actions that will attain these near-term and long-term scenarios.

## Key Findings

### *Technical Gaps and Challenges*

Technical gaps and challenges for critical materials reprocessing include:

1. **Verifiable tracking of critical materials within assembled devices:** Multifaceted supply chains for complex manufactured products do not typically require tracking of the types and volumes of specific component materials. Integration of existing technologies, with sufficient incentive for compliance in such tracking, can overcome this zeroth order issue. This gap includes an accepted list of critical materials, which can be sector-specific (e.g., battery manufacturing) or agency-specific (e.g., DoD).

2. **Technical complexity in recovery and reprocessing**: Similarity among critical materials in physical or electrochemical properties, especially among metallic elements characterized as lanthanides or actinids or among magnetic elements, complicates means to identify and cleanly separate specific elements. Recovery and reprocessing technologies based on magnetism or density of materials are insufficient for many currently critical materials. Innovative identification and separation technologies are required, with some challenges shared with and some distinct from those in mineral separations.

3. **Environmental impact:** Some current methods to reprocess metal and semiconductor elements, specifically at sufficient purity for manufacturing of new products, can include steps using or generating toxic chemicals. These steps can also affect the water supply, and in the U.S. are tightly regulated. Innovative methods to monitor and reduce adverse environmental impact in critical materials reprocessing from manufactured components will also benefit processing of raw materials.

4. **Design complexity:** High-tech, high-volume products ranging from military aircraft to smart phones are designed to maximize functional performance (and often to also minimize cost and weight). Design that includes end-of-life considerations including how critical materials within that product can be removed and reused is possible, but must be deliberate and requires innovation in digital manufacturing and in integrated computational materials engineering.

5. **Cost:** Recovery and reprocessing represent a new component to manufacturing of many advanced materials, with associated capital and personnel investments. Cost is often cited as an ill-quantified justification for why recycling is not more widely adopted. Technologies that can quantify and reduce this cost (e.g., labor intensive disassembly, tracking logistics, energy consumption for required final purity) for the DoD-focused supply chain and lifecycle will offer attendant cost reductions in civilian manufacturing supply chains.

## Recommendations

Recommendations to address the above technical gaps include the following. These recommendations will be instrumental in addressing technical gaps within a 5-year time horizon for a specific federal agency (DoD) as a targeted example with several interests shared with DOE and other federal agencies, as well as achieving the broader vision to revolutionize U.S. recovery and reprocessing of critical materials for diverse industry sectors.

1. **Direct, redirect and coordinate efforts of federally funded research and of public-private consortia, including a Manufacturing Center of Excellence for ARRT** (Gaps 2, 4): Advanced Recovery and Reprocessing Technology (ARRT) encompasses a range of basic science and economics research, as well as a range of manufacturing development & deployment programs. By considering the TLR/MRL1-4 efforts through this lens, new and current funding can be directed and coordinated to impact critical materials reprocessing technology. ARRT shares some challenges with those faced when extracting and processing of raw materials, but is focused on the challenges and advantages and economic analysis of reinserting manufactured materials back into the supply chain, for the same or other manufactured components. This redirection and coordination should include DARPA and DoD Scientific Research programs, NSF Engineering Research Centers and I/UCRC public-private research partnerships (including CR3), DOE Energy Innovation Hubs (including but not limited to CMI), and DOE Energy Frontier Research Centers, SBIR and other industry-targeted investments, and privately funded manufacturing sustainability consortia. This effort should also include a new Materials Manufacturing Center of Excellence (MCE), which could use existing public-private partnership mechanisms including but not limited to NSF Engineering Research Centers. Such interagency coordination now may lead to an ARRT public-private consortia enabling verifiable tracking, sector test beds for scale-up, and supply chain coordination among large companies and small-midsize enterprises.
2. **Scope a potential Manufacturing Innovation Institute (MII) for the NNMI** (Gaps 1-3): Recovery and reprocessing of multiple materials from manufactured components includes significant technical challenges at the TRL/MRL 4-7 levels, and requires sustained collaboration among several industry sectors and federal agencies. Scoping of pre-competitive topics through workshops, Requests for Information (RFIs), and interagency groups could facilitate a well-targeted NNMI Institute on this topic. The above analysis of technical gaps suggests that DoD could be an agency particular well-suited to launch and to benefit from such an institute with high national impact, with interests shared by ManTech, DDR&E, and DLA. However, recommendations to scope and launch such an NNMI-level effort for critical materials reprocessing and recovery RD&D are not limited to this federal agency.
3. **Develop an ARRT triage and tracking process,** through federal investment and public-private partnership (Gaps 1, 3-4): We recommend that this ARRT triage and tracking complement the R&D effort outlined in item 1, but focus on methods to prospectively identify emerging materials criticality. Such a triage process would use technical, economic, and market data to identify which critical materials (and purity levels or microstructures of those materials) are most amenable to leveraging this risk mitigation option. The resulting tools and findings are of particular use for federal agencies such as DoD, and thus DoD interests may provide a timely test case. However, proactive efforts will consider systems and not be limited to one material or one manufactured component, so that scenarios related to other manufacturing sectors or geopolitical changes can be addressed quantitatively. Here, the private sector and academia are partners in providing pre-competitive data and processes that guide the triage-based identification of emerging criticalities. This effort can be developed through a distinct MCE, or as part of a NNMI institute, the aims of which should be also scoped through RFIs. Such an MCE or NNMI institute effort prompts significant industry interest; it can provide a way for DoD to work effectively to address supply chain logistical issues with manufacturers, and can also provide economic, technical, and market analytical tools that are complementary to DOE CMI efforts.

4. **Increase workforce education and training in this skill set** (Gaps 1-2, 4): U.S. education and training in this area lags that of other nations, and lags that of other materials manufacturing innovation topics within the U.S.. This trend is despite high demand and high strategic interest in U.S.-based expertise and solutions. ARRT educational efforts to enable design of products and manufacturing methods that enable material recovery and reprocessing, including both hands-on and computational analysis, is required from the vocational technical training to community college certification to university / graduate school levels. This investment will create generations of U.S. workforce that mitigate materials criticality risk for industry, and that innovate sustainable product design for both civilian and military markets. Specifically, targeted Ph.D. fellowships in advanced materials manufacturing, and specifically in technical analysis of critical materials reprocessing, should be established by DoD and DOE as a subset of existing graduate fellowship programs. These could include training periods at federal and/or private U.S.-based sites of critical materials research and manufacturing, or at Manufacturing Technology Testbeds (MTTs) designed to test and optimize scalable technologies in this area.

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